IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1118

PETER H. FORSHAM, ET AL.,
Plaintiff-Petitioners,

v.

JOSEPH A. CALIFANO, JR., ET AL.,
Defendant-Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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Plaintiff-Petitioners respectfully request this Court to issue a writ of certiorari to the United States Court of Appeals for the District of Columbia Circuit to review its Judgment in the above-captioned case.

CITATIONS TO OPINIONS BELOW

The opinion of the United States Court of Appeals for the District of Columbia Circuit is not officially reported and is set out in Appendix B. The unreported Statement of Circuit Judge Bazelon as to why he voted for rehearing is set out in Appendix A. The Order of the United States District Court for the District of Columbia granting defendants' Motion to Dismiss is set out in Appendix C.

JURISDICTION

The Judgment of the United States Court of Appeals for the District of Columbia Circuit was entered on July 11, 1978. The Petition for Rehearing and the Suggestion for Rehearing En Banc were denied on October 17, 1978. Jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) to review the decision in the United States Court of Appeals.

QUESTION PRESENTED

Whether the District Court erred in finding that records derived from scientific research financed entirely by one government agency and forming the basis for action by another government agency are not "agency records" under the Freedom of Information Act, merely because the records are not housed within the physical confines of either agency.

STATEMENT OF THE CASE

This is an action brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2, to obtain records generated in the course of a scientific study conceived, directed, and entirely funded by The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD). This appeal by the plaintiffs challenges the order of the U.S. Court of Appeals for the District of Columbia Circuit affirming the District Court's dismissal of the action on the grounds that the records sought were not agency records under FOIA.

Introduction

Petitioners are three physicians who are members of the Committee for the Care of the Diabetic (CCD), an unincorporated association of approximately 200 physicians throughout the United States involved in the daily management and treatment of patients suffering from adult-onset diabetes mellitus, a disease affecting millions of Americans. Petitioners, and substantial numbers of the CCD members they represent, are not only active medical practitioners, but also leading teachers and researchers in the area of diabetology.

The records sought by plaintiffs consist primarily of specific data generated in the course of a federally-funded scientific study known as the University Group Diabetes Program (UGDP). A collaborative effort involving twelve scientific institutions around the country, the UGDP was originally formed in 1959 following a planning grant from NIAMDD. Beginning in 1960 and continuing to 1978, the UGDP has been awarded a series of NIAMDD grants totaling approximately fifteen million dollars to study the effectiveness of oral hypoglycemic drugs in preventing the complications of diabetes mellitus.

In a monograph published in December 1970[1] the UGDP reported its conclusions based on the first eight years of the study. The principal conclusion was that the combination of diet and oral medication was no more effective than diet alone in prolonging life. Also suggested was a possible correlation between oral medication and cardiovascular mortality.

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[1] "The UGDP: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes", *Diabetes*, 19:2, 747-830.

Release of the UGDP conclusions triggered an immediate and large-scale controversy among physicians and scientists. Professional conferences were convened, articles were published and scientific studies, albeit of a more limited scope, were undertaken with the hope of evaluating the UGDP conclusions and determining their validity. Rather quickly, the dialogue turned into a debate with the medical and scientific communities dividing sharply along pro- and anti-UGDP lines. Supporters of the UGDP pointed to the study's cost, duration, broad patient base, and sophisticated design, as confirming the validity of the findings.[2] UGDP critics, on the other hand, cited numerous inadequacies in study design, methodology, and execution, not the least of which was an apparent breakdown in initial randomization which had led to a far greater predisposition to cardiovascular risk in hypoglycemic-treated subjects than in control group subjects.[3]

The scientific debate took on an added dimension when a UGDP investigator resigned from the study and challenged the integrity of the study's data base (Rec-

[2] For example:

Cornfield, The University Group Diabetes Program: A further statistical analysis of the mortality findings, *JAMA* 217:1676-1687, 1971.

Prout, Knatterud, Meinert, et al., The UGDP Controversy: Clinical trials versus clinical impressions. *Diabetes* 21:1035-1040, 1972.

[3] For example:

Feinstein, Clinical Biostatistics: VIII. An analytical appraisal of the University Group Diabetes Program (UGDP) study. *Clin. Pharmacol.* 12:167-191, 1971.

Schor, The University Group Diabetes Program: A statistician looks at the mortality results. *JAMA* 217:1671-1695, 1971.

ord page 6, Exhibit A).[4] The data in question (hereinafter raw data) were the results of the various tests administered to UGDP subjects at the beginning of the study and on a quarterly basis thereafter to assess the relative efficacies of the treatments under investi-

[4] This UGDP investigator, Angela Bowen, M.D., testified as follows before FDA at the public hearings on the proposed labeling change for oral hypoglycemic drugs on August 20, 1975:

> An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "were the data that were gathered in the field accurately and honestly recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or other side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. [Tolbutamide is an oral hypoglycemic drug and a competitor of phenformin.] It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstances was discussed at length. This ended with the demand from the New York delegation that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfield and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators.

gation. Recorded onto standardized forms, copies of the raw data had been periodically forwarded from each clinical center to the UGDP Coordinating Center at the University of Maryland where they were collected, coded, punched, and stored on magnetic discs to allow for rapid computer access and analysis. Since all data analysis was conducted at the Center under the direction of respondent Christian R. Klimt, and since all UGDP reports, including the 1970 monograph, were prepared at the Center, a challenge to the raw data was a challenge of the entire validity of the study as reported.

Even before the publication of the UGDP conclusions, the Food and Drug Administration (FDA) began issuing press releases and circulating Drug Information Bulletins to physicians around the country with the agency's revised position on the proper treatment of diabetics based on the UGDP. CCD was organized immediately thereafter in an effort to assure that both the patients who suffered from diabetes mellitus and the physicians who treated it were provided with full, accurate, and truthful information concerning the safety and efficacy of the various treatment modalities. CCD became concerned that such premature FDA recommendations would create anxiety for diabetics and confusion for their physicians. In a telegram to the FDA entitled a "Statement on the Treatment of Diabetes" (Record page 1, Exhibit S), CCD deplored the fact that physicians had been provided no basis for making their own assessment of the validity of the UGDP and requested that:

> before any further action is taken by regulatory agencies, the [UGDP] raw data should be made available to the scientific community at large.

In a subsequent exchange of correspondence with the FDA, CCD renewed its request for an independent review of the raw data, while the FDA endorsed the UGDP based on an allegedly "full and careful evaluation" of this study's conclusions (Record page 1, Complaint ¶ 12). When shortly thereafter the FDA proposed relabeling of all oral hypoglycemic drugs to reflect UGDP conclusions, CCD petitioned the FDA to rescind its proposal and to withhold further action pending independent corroboration of the study. In its petition, CCD presented a detailed critique of UGDP conclusions and again requested access to the raw data both for itself and other qualified researchers.

The FDA denied CCD's petition on June 5, 1972, and again endorsed the reliability of the UGDP. However, in response to CCD's request for access to the raw data, the FDA responded as follows:

> Your petition states that the results of the UGDP study are not available and therefore not subject to the usual critical review. *We have been assured that the UGDP personnel will honor any reasonable request for data and information.* (Record page 1, Complaint, ¶ 12) (Emphasis supplied).

However, UGDP personnel were not responsive to requests for access to the raw data, even from investigators associated with the UGDP (Record page 6, Exhibit A). Consequently, when the FDA re-initiated its attempts to require relabeling of oral hypoglycemic drugs based solely on the UGDP, CCD brought an action in the United States District Court for the District of Massachusetts to enjoin such relabeling and to require production of the raw data. *Bradley* v. *Richardson,* No. 72-2517-M (D. Mass., 1972).

A preliminary injunction issued enjoining the proposed relabeling, from which order the FDA appealed. In its opinion on July 31, 1973, the First Circuit Court of Appeals remanded the labeling question to the FDA while expressing in *dicta* CCD's entitlement to the raw data as being part of the administrative record. *Bradley* v. *Weinberger,* 483 F.2d 410 (1st Cir. 1973). However, the FDA deferred further action on the labeling pending a report from the Committee of the Biometric Society which had been reviewing the scientific quality of the UGDP at NIAMDD request. Under its charge from NIAMDD, the Biometric Committee had been:

> urged to utilize all the resources it needs to arrive at a satisfactory answer, and to prepare a report for publication . . . . Although no prior approval by the NIH is required, we shall expect to be kept informed of the conclusions as they develop. (Letter from Robert Q. Marston, Director of NIH, to Colin White, Committee Chairman, June 9, 1972, quoted in "Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents", *Journal of the American Medical Association,* 131 JAMA 615, February, 1975 (hereinafter Biometric Report).

The fact that the Committee did not issue its final report until two and one-half years after its original charge contributed to rumors of sharp division among its members along familiar pro- and anti-UGDP lines. CCD was informed that the Committee had actually prepared an earlier draft of its report which NIAMDD had opposed due to its criticism of the Institute-sponsored study. The final Biometric Report, as published, endorsed many of the arguments on both sides of the controversy and concluded with "moderately strong" support for the UGDP. *Id.,* at 655.

Particularly relevant for purposes of FOIA is that pursuant to contract with NIAMDD, the Biometric Committee was afforded access to the raw data in the course of preparing its report. To be sure, such access was limited, since the data pertained to only one of the oral hypoglycemics studied and even then only up to October 1969 (two Committee-imposed limitations which may themselves have diminished the ultimate value of the report). Nonetheless, the UGDP raw data had been made at least partially available to persons outside of the UGDP and as a result of a government contract.

After the December, 1975 announcement by FDA of their intention to audit the raw data, a long period of official silence was maintained as to the status of the audit. During the oral argument in this FOIA action before the Court of Appeals in December 1976, government attorneys promised that all raw data which would come into FDA hands during the audit would be released under FOIA. However, despite unofficial indications that the data review phase of the audit had been completed, no data was forthcoming to the public.

On July 25, 1977, Health, Education, and Welfare (HEW) Secretary Califano suspended phenformin hydrochloride, an oral diabetes medication, as an "imminent hazard to public health" pursuant to 21 U.S.C. § 355(e). In his Order suspending the drug, Secretary Califano stated that he placed a primary reliance on the UGDP data in his decision and on the FDA's endorsement of the study.[5]

The full administrative hearing on the drug withdrawal issue which followed the suspension of phen-

[5] Order of Secretary Califano Suspending Phenformin, at pp. 38, 40-41.

formin hydrochloride reached the oral testimony phase on October 4, 1977. Prior to the first day of testimony, all participants at the hearing, including FDA, submitted a signed statement required by regulation (21 C.F.R. § 12.85) that all documents and data in their files relevant to the case and upon which they relied had been submitted. FDA submitted no UGDP data or audit findings—only a copy of the published UGDP reports.

The CCD physicians, participants at the phenformin hearing, filed objections to the presiding Administrative Law Judge based on the FDA omission of the UGDP data. On October 6, 1977, the Administrative Law Judge ordered FDA to come forward with whatever UGDP data was in their possession. On October 7, 1977, the final day of the phenformin hearing, FDA presented the participants with several thousand pages of data gained through the FDA audit of the UGDP. These materials did not represent all raw data the FDA personnel had viewed at the coordinating center, but rather those parts of the raw data that were transcribed on FDA forms and carried back to FDA offices or directly transferred to government premises through a computer link-up. FDA attorneys stated on October 6, 1977 that the FDA audit findings, based on the submitted raw data, were in final draft stage but were not ready for submission.

After several months of informal efforts to gain public access to the audit report, CCD, on July 10th, 1978, made a renewed formal request for the report through FOIA. This request was denied on August 6th, 1978, with the statement that the report was still in draft form and was an investigative document and thereby exempt under FOIA.

On November 14, 1978, FDA published in the *Federal Register* (43 F.R. 52732) a notice of public availability of the audit report concurrently with a reissuance of proposed regulations which declared FDA's intention to relabel the oral hypoglycemic drugs—the same Federal action which CCD had challenged with the inception of the organization in 1970. In correspondence attached in an appendix to the audit report, a letter of transmittal of Fall 1977 was noted which had served to forward to the UGDP coordinating center the draft FDA audit report, which was denied to CCD as an investigative document nine months later.[6]

Controversy on the serious medical issues surrounding the UGDP has continued to date. A principal investigator at one of the UGDP clinics published results of his analysis of the UGDP data in the *Journal of the American Medical Association* on January 5, 1979.[7] Those recent findings refuted the previously published results. The UGDP investigator performing this analysis had applied the partial data which could be made available to him from the UGDP clinics. The UGDP coordinating center had denied him access to the complete records, containing all the raw data, kept in a bank vault in Maryland.

Lower Court Proceedings

On September 30, 1975, plaintiffs filed a complaint under FOIA seeking production of the UGDP raw data and the draft Biometric Report. The complaint also sought a declaratory judgment that the withholding of the requested records both by the federal defend-

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[6] The FDA audit report contained no new unreleased UGDP data.

[7] Kilo, Letter to the Editor, JAMA 241:26 (1979).

ants and by defendant Klimt was unlawful (Record page 1, Complaint ¶¶ 1, 2).

On November 21, 1975, the federal defendants moved to dismiss and/or for summary judgment. Despite the fact that fully five years earlier a regulatory action had been taken by the federal government ostensibly based on the UGDP data, accompanying federal defendants pleadings were the affidavits of the Assistant Secretary for Health for HEW and the Director of NIAMDD stating that no officer or employee within HEW or its subagencies ever had or saw the raw data and that in their judgment such data were not agency records under the provisions of FOIA (Record page 4, Exhibits 1 and 3).

On February 5, 1976, the Court dismissed plaintiffs' complaint for FOIA relief against the federal defendants and granted federal defendants' motion to dismiss.

On February 25, 1976, petitioners filed a Notice of Appeal of the District Court decision with the U.S. Court of Appeals for the District of Columbia Circuit. The case was argued before Circuit Judges Bazelon, Leventhal and MacKinnon on December 6, 1976.

Judge Leventhal, in the Opinion of the Court issued July 11, 1978, declared as the governing principle that only if a federal agency has created or obtained a record in the course of doing its work is there an agency record that can be determined under FOIA.[8] Further interpreting this newly announced standard, Judge Leventhal stated:

> Where records are created by a private entity, we believe the applicability of FOIA will turn on whether the government is involved in the core planning or execution of the program, or whether, by contrast, the entity retains its private character in bona fide fashion during the course of the endeavor that results in the records. (Opinion of the Court, at 16, fn. 19)

[8] Opinion of the Court, at p. 16.

The dissenting opinion of Judge Bazelon stated that the UGDP data were agency records for the purposes of FOIA. He cited the federal government funding of the UGDP, access to the raw data and reliance on the raw data as proof of the significant government involvement with the records required to make them agency records.

Petitioners filed a Motion for Rehearing and Suggestion for Rehearing En Banc, citing the extensive government involvement in the core planning and execution of the UGDP study which qualified the UGDP raw data as agency records under the rule announced in the majority opinion. Among the factors raised by petitioners to meet this new agency records test were the following: (1) the two year NIH planning grant which initiated the UGDP study and resulted in the creation of the plan for research; (2) the unusual degree of federal input into the ongoing study (This included a special UGDP Policy Advisory Board headed by an employee of NIH which took initiatives in directing the course of the study.); (3) the exercise of federal audit powers twice during the study; and (4) the primary mission of the UGDP Coordinating Center to coordinate grant research. The center coordinated three other major federal grants which created a continuing multi-million dollar federal commitment to the center's computer data storage and retrieval systems.

The petitions for rehearing were denied on October 17, 1978. Judge Bazelon voted for rehearing noting that

> Plaintiffs make a strong case that, from the inception of the study, the government involvement in planning and execution has been pervasive. (Statement for Rehearing, p. 2)

Further, Judge Bazelon noted in reviewing the course of the litigation,

> Plaintiffs could not previously have known precisely what showing was required under the majority's novel criteria for determining whether the data were agency records. *Id.*

Petitioners request that this Court accept jurisdiction to resolve the legal issues presented herein, and, if necessary, guide the lower courts' consideration of this case on remand.

Reasons for Granting the Writ

This petition raises important questions concerning the administration of the Federal Freedom of Information Act (FOIA), 5 U.S.C. § 552. These questions concern the definition and character of "agency records" under FOIA. The particular issue involved has not been considered by this Court.

The legal issues described herein arise within a factual setting with the very broadest implications for millions of diabetic patients. Whether the UGDP Coordinating Center's published results are truly consistent with the data collected is a question with critical ramifications for diabetic patients. Diabetes mellitus is a progressive degenerative disease which dictates that treatment for the condition is a continual daily battle to combat its effects. The published UGDP findings have been and continue to be the subject of federal regulatory action and policy requiring changes in the diabetic patient's treatment regime. Some of these federal positions are based *solely* on the UGDP. The risk of a misapplication of the study's data is a generation or more of diabetic patients receiving improper treatment—an irreversible tragedy which could be prevented by a full analysis of the data.

I. THE RAW DATA ARE AGENCY RECORDS BECAUSE THEY ARE THE PRODUCTS OF RESEARCH CONCEIVED, FUNDED AND SUPERVISED BY NIAMDD AND CARRIED OUT THROUGH ITS PARTNERSHIP RELATIONSHIP WITH THE UGDP.

A. The Products of Government Funded Projects Are Not the Exclusive Preserve of the Individual Producing Them and Are Therefore Not His Property.

The concept of "property" involves rights which one can exert to the exclusion of others, *Black's Law Dictionary* 1382 (Rev. 4th ed., 1968):

> . . . the unrestricted and exclusive right to a thing; the right to dispose of a thing in every legal way, to possess it, to use it, and *to exclude everyone else from interfering with it.* (Emphasis supplied)

It is uncontested here that the UGDP Coordinating Center presently has "possession" and "custody" of the raw data. Mere possession and custody, however, do not translate into "property", for while they permit the Center a more immediate impact on the data they do not confer upon it exclusive authority. In fact, traditionally, the product of work performed within the scope of government duties belonged entirely to the government. As first enunciated by the Supreme

Court in *Solomons* v. *United States,* 137 U.S. 342, 346 (1890), the principle was as follows:

> If one is employed to devise or perfect an instrument, or a means for accomplishing a prescribed result, he cannot, after successfully accomplishing the work for which he was employed, plead title thereto as against his employer.

This approach was further developed in the landmark case of *Houghton* v. *United States,* 23 F.2d 386 (4th Cir.), *cert. denied,* 277 U.S. 592 (1928), where a chemist employed by the Public Health Service patented a fumigant gas to which the government claimed title. The Court rejected the chemist's contention that the government had only limited property rights in the fumigant, since the invention had been the very purpose of the research for which the chemist had been hired and compensated. The Court also pointed out that considerable amounts of government resources, including research equipment and staff, had been expended on the project. Moreover, even beyond the particular financial interests of the government in the research was the inherently public nature of the entire undertaking:

> *The Public Health Service represents the people of the United States. Its interest is their interest. Its inventions and discoveries are made for their benefit.* . . . In the case of the fumigant gas developed by the defendant while employed and paid by the government to develop it, they are interested, not only in the use which the Health Service itself may make of it, but also primarily in having it supplied to the public as freely and cheaply as possible. *It is unthinkable that, where a valuable instrument in the war against disease is developed by a public agency through the use of public funds, the public servants employed in its production should be allowed to monopolize it for private gain* and levy a tribute upon the public which has paid for its production, upon merely granting a nonexclusive license for its use to the governmental department in which they are employed. *Id.* at 391. (Emphases supplied)

The principles of *Houghton* have been widely accepted and followed. *Sawyer* v. *Crowell Publishing Co.,* 142 F.2d 497 (2d Cir. 1944), *cert. denied,* 323 U.S. 735 (1944); *United States* v. *First Trust Co. of Saint Paul,* 251 F.2d 686 (8th Cir. 1958); *Public Affairs Associates* v. *Rickover,* 268 F. Supp. 444 (D.D.C. 1967).

The courts have applied *Houghton* principles to the case of government employment of independent contractors as well as employment of its own employees. In *Mine Safety Appliances Co.* v. *United States,* 364 F.2d 385, 391 (Ct. Cl. 1966), the Court found that a crash helmet developed at a private university out of privately funded research was so integrally related to the university's research contract with the U.S. Navy as to confer upon the government a royalty free license to use the helmet. Even though the invention was not specifically contracted for, it was held to be within the implied scope of the contract and a direct consequence of its performance. "There was a close and umbilical connection which was not, and could not be, severed."

The same rule was applied in *Technitrol, Inc.* v. *United States,* 440 F.2d 1362, 1372 (Ct. Cl. 1971), involving a magnetic disc storage system developed in the course of a computer research contract between the U.S. Army and the University of Pennsylvania:

> The Federal Government has the right to use, royalty-free, those ideas, improvements, discoveries, and inventions—crystallized during perform-

ance of the federal contract—which have a "close and umbilical relationship" to the work and research funded by the United States.

This property right of the government to the benefits of government-sponsored research encompasses records generated in the course of research as well as the final research product. In *Jacobs* v. *United States,* 239 F.2d 459 (4th Cir. 1956) *cert. denied,* 77 S. Ct. 666 (1957), the Court upheld the government's claim to preliminary records and drawings produced in the course of its contract for the development of a bombing system, citing *Houghton.* Even beyond the terms of the contract, this right was founded separately on fundamental considerations of equity:

> [I]t is clear that, without regard to the contract, the government is entitled to the benefit of all knowledge gained by the contractor in the course of the research for which the government was paying him. (at 461)

Applying the foregoing principles to the question of rights to the data at issue, it is apparent that neither the UGDP investigators nor the Coordinating Center have an exclusive property right. Therefore, an analysis of the FOIA issues in this case which focuses on possession and property rights is inappropriate for this case.

B. By Virtue of the Partnership Relationship Between NIAMDD and the UGDP, the Government Has a Property Right In the Raw Data of the Study and An Unrestricted Right of Access.

In addition to the history of interaction between HEW and the UGDP Coordinating Center, the partnership relationship is evidenced by an elaborate regulatory structure.

HEW's general policy on public access to grant research is stated as follows:

> the public interest will . . . be best served if intensive advances resulting [from research grants] are made freely available to the Government, to science, to industry, and to the general public. 45 C.F.R. § 8.0.

And again:

> It is the general policy of the Department that the results of Department research should be made widely, promptly, and freely available to other research workers and the public. 45 C.F.R. § 6.1.

More specifically, NIH officials are authorized access to

> any books, documents, papers, and records of the grantee which (are) determined . . . pertinent to a . . . grant for the purpose of making *audit, examinations, excerpts, and transcripts.* 45 C.F.R. § 74.23(a). (Emphasis supplied)

Additionally, in cases where records located outside the agency are determined to have long-term retention value, they can be ordered physically transferred to government custody. 45 C.F.R. § 74.20(b). The government retains a permanent unrestricted license to use the products of the scientific endeavor. 45 C.F.R. § 8.1. Moreover, the public at large has its own rights of access to grantee records, which can be restricted only in specified instances. 45 C.F.R. § 74.24. The cumulative impact of these HEW regulations establishes the government's dominion and control, and thereby access, to the UGDP data justifying petitioners' demand for the raw data under FOIA.

II. RECORDS PRODUCED UNDER AGENCY SPONSORSHIP AND IN FULFILLMENT OF AGENCY RESPONSIBILITIES ARE AGENCY RECORDS UNDER THE FOIA IRRESPECTIVE OF THEIR PARTICULAR PHYSICAL LOCATION.

It is well established that records need not be prepared within the physical confines of an agency to be agency records under the FOIA. *Washington Research Project, Inc.* v. *DHEW,* 164 U.S. App. D.C. 169, 504 F.2d 238 (D.C. Cir. 1974), *cert. denied,* 95 S. Ct. 1951 (site visit reports prepared by outside consultants appointed to assist NIH in making grant determinations are agency records); *Wu* v. *National Endowment for Humanities,* 460 F.2d 1030 (5th Cir. 1972) (memoranda and other work products prepared by outside consultant to recommend course of agency action on grant application are agency records).

Further, once a document is generated by or on behalf of an agency, it does not lose its identity as an agency record merely because it ceases to reside within the agency's physical confines. In *EPA* v. *Mink,* 410 U.S. 73 (1973), plaintiffs sought access to reports prepared by the EPA which had been forwarded to the President's office. While custody of the materials was in the President, this did not divest them of their status as EPA records under the FOIA. Similarly, in *Soucie* v. *David,* 145 U.S. App. D.C. 144, 448 F.2d 1067 (D.C. Cir. 1971), records prepared by the Office of Science and Technology were held to be agency records even though no longer located within the agency.

The issue of agency records was examined in detail in *Nixon* v. *Sampson,* 389 F. Supp. 107, 147 (D.D.C. 1975), where plaintiff Nixon contended that materials generated by him and then currently located in the White House Office were not agency records under the

FOIA. The court acknowledged that the situs of the records was not in an agency but held that since the records were generated under the auspices of an agency, the Executive Office of the President, they remained agency records irrespective of location. As the court stated, the housing of records beyond agency confines

> does not mean that [they] are immune from access under the FOIA. . . . Therefore, the FOIA plaintiffs are entitled to a declaration that they are "records" within the meaning of the FOIA. (citations omitted).

The public interest in scientific endeavor was acknowledged by the Court in *Washington Research Project, supra,* where a variety of grant-related materials pertaining to HEW-sponsored research were held to be subject to FOIA disclosure due to their factual and investigative nature. The court was well aware that particular scientists may have "a preference for or an interest in nondisclosure", *Id.* at 245, but ruled that to restrict such materials from public access was antithetical to the mandate of the FOIA as well as to the "philosophical values of science", *Id.* at 244.

The HEW response to *Washington Research Project* has particular relevance here, since it has confirmed beyond question the availability of the records requested. Prior to the decision, HEW regulations listed "raw research data" among grant-related materials "generally not available" under the FOIA. However, that restriction was removed by HEW when it amended its FOIA regulations to bring Department policy into conformance with the law of the case (40 F.R. 18997, May 1, 1975). There remain, therefore, no lawful restrictions on petitioners' rights of ac-

cess under applicable agency regulations; and under traditional FOIA principles, information not explicitly exempt must be publicly disclosed.

While demonstration of need is not required under the FOIA, the interest in disclosure of scientific data has been enunciated clearly:

> The public's need for information is especially great in the field of science and technology, for the growth of specialized scientific knowledge threatens to outstrip our collective ability to control its effects on our lives. *Soucie* v. *David,* 145 U.S. App. D.C. 144, 448 F.2d 1067, 1080 (D.C. Cir. 1971)

In a case recently decided in the Federal District Court for the District of Columbia, *Public Citizen Health Research Group* v. *Department of Health, Education, and Welfare et al.,* 449 F. Supp. 937 (D.D.C. 1978), the records of a Professional Standards Review Organization (PSRO) were ordered subject to FOIA requests. PSROs monitor the medical profession and collect information on physicians and patients. This case is important for its refusal to limit the reach of FOIA where scientific, medical records, often of a sensitive, personal nature, are involved. The Court referred objections on the nature of the documents to the protections afforded by the FOIA exceptions. The basic applicability of FOIA is not to be affected.

After ruling that the PSRO records were agency records, the Court, in *Public Citizen Health Research Group* stated

> While HEW has neither possession nor control of the records sought, its administrative process for processing the request can and perhaps should be used . . . (At 941)

Thus, as in the case at bar, a federal agency is required to retrieve records from outside the agency for FOIA disclosure.

III. THE RAW DATA ARE "AGENCY RECORDS" BECAUSE THEY ARE SUBJECT TO ACCESS BY THE FDA FOR AUDIT AND OTHER PURPOSES AND ARE THE BASIS FOR AGENCY ACTION.

A. FDA Has Access and Control Over the UGDP Data Through Its IND Regulations.

During the course of the UGDP controversy, CCD's efforts to obtain access to the raw data have met first with evasive, then with technical, and then increasingly negative responses from the FDA. The Agency's original position was to encourage CCD's independent examination of the raw data in the candid recognition that UGDP results could not be subjected to the usual critical review. The FDA assured CCD

> that the UGDP personnel will honor any reasonable request for data and information (Record page 1, Complaint ¶ 12).

However, as the controversy developed and the UGDP Coordinating Center did not honor requests for data even from its own principal investigators,[9] plaintiffs again requested the data under FOIA. The agency response was simply to channel the matter to NIAMDD. No longer was the Agency acknowledg-

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[9] As reported by Dr. Bowen:

> . . . My co-investigator requested from the coordinating center a printout of the data from our clinic to determine whether it agreed with our own data kept in the clinic. That request, like all other requests, was refused. The jealousy with which access to the data has been guarded to all who have requested it is not reassuring (Record page 6, Exhibit A).

ing its own role relative to a study which it had adopted and on which it was basing regulatory action.

A different agency position was articulated in the Agency's final denial of petitioners' request for access to the raw data. In this communication (Record page 1, Exhibit Q), the Agency claimed that it had no *authority* to order production of such data, and that the FDA's proposal to relabel oral drugs was based solely on the UGDP report as distinguished from the underlying data.

For the FDA to deny its authority over the data is to overlook the plain meaning of its regulations relative to investigational new drugs (IND's). These regulations fully authorize the "inspection and copying" of investigators' clinical records simply upon FDA request. 21 C.F.R. § 312.1. Since the UGDP holds two IND approvals from the FDA, (Record page 1, Exhibit U), UGDP data are directly subject to the right of the Agency to inspection and copying.

The attenuated nature of the FDA position here is illustrated by its own FOIA regulation *requiring* the disclosure of raw scientific data to the public in the case of FDA-sponsored research.

> Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed. 21 C.F.R. § 20.105(d).

The FDA regulations hold the products of extramural research are "agency records" in the same manner as that of intramural research.

In short, the data sought by plaintiffs would fall squarely within the scope of FOIA had the UGDP been funded by FDA rather than by NIAMDD. It

defies common sense as well as the broad purposes of FOIA to permit the end result to be determined by which of HEW's operating agencies actually funded the study, particularly where the agency whose procedures would have mandated production of the raw data is the agency placing reliance on the data to support a broad range of regulatory policies.

B. FDA Reliance On the UGDP Raw Data, Combined With Its Control Of and Access to the Raw Data Require Release Of the Raw Data Under FOIA.

As noted by Judge Bazelon in his dissenting opinion in this case, UGDP raw data have been "absorbed into the federal decision making process." (At 16, fn. 21) FOIA was designed to give the public access to this kind of data which underlies government processes.

However, the Concurring Opinion, at page 2, states that no public harm will result from the denial of public access to UGDP data in view of possible availability of subpoena authority in this matter. The shortcomings of this suggested alternative and the further litigation it contemplates reinforces the importance of FOIA access in this case. The situation with phenformin is illustrative. On July 25, 1977, the Secretary of Health, Education, and Welfare declared phenformin an imminent hazard and summarily banned it from general use without prior hearing or disclosure of any of the raw data on which the Order was based. This order was carried throughout the medical and lay press and caused confusion and alarm for thousands of diabetic patients and their physicians. While this Order was challenged by petitioners and others in concurrent administrative and judicial proceedings, these challenges are still pending at the present time,

and no final decisions have been rendered.[10] After nearly 16 months since all diabetic patients were required to be removed from phenformin largely on the basis of the UGDP, no forum, administrative or judicial, has determined the merits of petitioners' challenge to the Order or petitioners' right to the UGDP raw data. Thus while after-the-fact litigation may theoretically be an alternative way of securing access to the data, it lacks the timeliness and expeditiousness of an FOI request as well as the capacity to prevent needless confusion, alarm and changes in treatment among diabetics and their physicians.

Perhaps the best explanation of this principle has been made by HEW in another context. Secretary of HEW, Joseph Califano, on March 17, 1978 in testimony submitted to the Subcommittee on Health and Scientific Research of the Senate Human Resources Committee, discussed the HEW proposal to require public access to research data generated by private drug companies. He stated:

> We support the release [of this data] because we believe that FDA's decision making will benefit from the comments of scientists, representatives of patient organizations, and other interested members of the public. We also believe that disclosure of the basis for FDA's decisions will increase the credibility of those decisions with the Congress, the scientific community, and the public. Disclosure will probably lead to some increase in controversy over particular decisions, but in the long run we believe that controversy over FDA decisions will decrease as the basis for those decisions becomes better and more widely understood.[11]

[10] In *Forsham et. al* v. *Califano*, No. 77-1478 (U.S. District Court for the District of Columbia) and Nos. 77-2072 and 78-2288 (U.S. Court of Appeals for the District of Columbia Circuit), petitioners and other concerned physicians and diabetic patients are contesting FDA actions concerning phenformin which rely on the UGDP data.

Additionally, Secretary Califano indicated that the duplicative testing that would result from a failure to release important drug data would "potentially expose humans to unnecessary (and therefore ethically questionable) drug testing" and "waste scarce scientific resources."[12] Therefore in the situation of privately funded research for a commercial purpose in which a company has a true proprietary interest, HEW would favor statutory public access. However, in this case, with 100% federal funding, an avowed public purpose, non-replicable research data, government reliance and a network of regulations which grant authority for release of the data, HEW has chosen a converse policy to that of public disclosure. Such inconsistency is neither appropriate nor in the public interest.

[11] Proposed Drug Regulation Reform Act of 1978: Hearings on S.2755 Before the Subcommittee on Health and Scientific Research of the Senate Human Resources Committee, 95th Congress, 2nd Session (Statement of Joseph Califano), at p. 16.

[12] *Id.*, at p. 14.

CONCLUSION

For the reasons set forth above, the petition for writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A

Notice: This opinion is subject to formal revision before publication in the Federal Reporter or U.S. App. D.C. Reports. Users are requested to notify the Clerk of any formal errors in order that corrections may be made before the bound volumes go to press.

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, et al., APPELLANTS

v.

JOSEPH A. CALIFANO, JR., Secretary of the Department of Health, Education and Welfare, et al.

On Petition for Rehearing

Filed October 17, 1978

Before: BAZELON, LEVENTHAL and MACKINNON, *Circuit Judges*

ORDER

Upon consideration of appellants' petition for rehearing, it is

ORDERED, by the Court, that the aforesaid petition for rehearing is denied.

Per Curiam

Circuit Judge Bazelon voted to grant rehearing for the reasons set forth in the attached statement.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Statement of BAZELON, *Circuit Judge, as to why he voted for rehearing*: In their petition for rehearing, the physicians who requested the UGDP data point out the unusual degree of federal involvement in the initiation and conduct of the UGDP study, which, even under the approach taken by the majority, would bring these data within the scope of "agency records." Specifically, plaintiffs suggest that rather than an independently conceived project by scientists who "developed their own methodology," *see* Maj. op. at 20, the UGDP study was in fact initiated by NIH, which was responsible for developing the research protocol. Petition for Rehearing at 4. Moreover, as a condition of the renewal of the UGDP grant, NIH established a Policy Advisory Board, which, according to plaintiffs, "took initiatives in directing the course of the [UGDP] study," further evidence of government involvement in the on-going UGDP research. *Id.* at 3-4.

The majority opinion notes that "where records are created by a private entity, we believe the applicability of FOIA will turn on whether the government is involved in the core planning or execution of the program." Majority op. at 16. Plaintiffs make a strong case that, from the inception of the study, the government involvement in planning and execution has been pervasive.

Thus, in addition to the reasons set forth in my dissenting opinion, plaintiffs' contentions might well furnish an additional basis for finding these data to be "agency records." Plaintiffs could not previously have known precisely what showing was required under the majority's novel criteria for determining whether the data were agency records.[1] They have now raised a significant

[1] According to the majority, government involvement in the "core" of a program, see Maj. op. at 16 n.19, 21 is the key to determining whether records created by private individuals or groups are "agency records", which appears to be the first use of that concept in connection with the definition of agency

factual question which, under the majority's approach, warrants a remand to determine the degree of NIH involvement in the initiation and conduct of the UGDP study, rather than an affirmance of the district court, which had focused exclusively on the physical possession and ownership of records.[2]

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records under FOIA. *Cf.* Ciba-Geigy Corp. v. Mathews, 428 F. Supp. 523 (S.D.N.Y. 1977) where the district court, considering another FOIA request for the UGDP data noted that "[t]here is little official authority to aid the Court in discerning whether documents are agency records." *Id.* at 529. It is noteworthy that the principal authority which "lighted" the majority's path was not even a FOIA case, but an action under the Federal Tort Claims Act. See Maj. op. at 12-13, discussing United States v. Orleans, 425 U.S. 807 (1976).

[2] Admittedly, the contentions raised in the petition for rehearing are somewhat conclusory. If, however, the plaintiffs lack factual support sufficient to show government involvement in the core of the program, the district court will then be justified in dismissing the suit.

A far less satisfactory course would be to permit plaintiffs to elaborate their contentions on rehearing in this court. Such supplementation would not consist of adducing evidence, but would more closely resemble a proffer, designed to permit us to assess whether a remand in lieu of affirmance would be any more than a formal gesture. I believe that this approach is inferior to directly remanding this case to the district court because the questions involved are largely factual, and to explore them here may work substantial prejudice to both sides by denying them the opportunity to develop the relevant facts through further investigation, discovery and stipulation in the district court. Only with such a record can a court adequately judge the degree of NIH's involvement in the "core" of the UGDP study. However, I do not believe that we should cut off all avenues for the plaintiffs to show the requisite degree of government involvement in initiating and directing the UGDP study, and therefore I voted for rehearing.

APPENDIX B

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, et al., APPELLANTS

v.

JOSEPH A. CALIFANO, JR., Secretary of the Department of Health, Education and Welfare, et al.

Appeal from the United States District Court for the District of Columbia

(D.C. Civil 75-1608)

Argued December 2, 1976

Decided July 11, 1978

Harvey W. Freishtat, with whom *Anthony J. Roccograndi* was on the brief, for appellants.

Michael Kimmel, Attorney, Department of Justice, with whom *Rex E. Lee*, Assistant Attorney General, *Earl J. Silbert*, United States Attorney and *Leonard Schaitman*, Attorney, Department of Justice, were on the brief, for Federal appellees.

Mary Elizabeth Kurz, Assistant Attorney General of the State of Maryland, with whom *David H. Feldman*, Assistant Attorney General of the State of Maryland was on the brief, for appellee, Klimt.

Before: BAZELON, LEVENTHAL and MACKINNON, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* LEVENTHAL.

Concurring opinion filed by *Circuit Judge* MACKINNON.

Dissenting opinion filed by *Circuit Judge* BAZELON.

LEVENTHAL, *Circuit Judge*: In its broad aspect this appeal presents the question whether and under what conditions data compiled by a private group that is receiving money under a federal grant-in-aid program are or become "agency records" by virtue of the fact that the agency has funded the program and has the authority to demand those records.

An action was brought by specialists in the treatment of diabetes, as individuals and a committee,[1] to obtain raw research data of the University Group Diabetes Program (UGDP). The program is a privately conducted and federally funded long-term clinical study of the treatment of diabetes, that has reported certain harmful consequences attendant upon the long-term use of oral hypoglycemic agents. Plaintiffs question the validity of the study, and are concerned lest a useful therapeutic tool be unnecessarily removed from the market. They

[1] Three physicians sue in their own behalf, and in behalf of the Committee on the Care of the Diabetic, described in the complaint as an unincorporated association of 178 physicians involved in the daily treatment and management of diabetes.

seek access to the raw data in order to implement their challenge to the study's validity.

The action was brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. That Act is addressed to each "agency" of the Federal Government as defined.[2] Broadly speaking, and subject to exceptions, it directs each agency to make available to the public certain information, and also "agency records." It establishes the District Court's "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B).

A. Background

1. *The UGDP Study and the Sponsoring Institute*

The UGDP is a study funded by 13 federal grants administered by the National Institute of Arthritis, Metabolism and Digestive Diseases (hereafter sometimes Institute or NIAMDD). That institute is an "agency" under the Act, being part of the National Institutes of Health, which in turn is an organization within the Public Health Service, in the Department of Health, Education and Welfare. The grants were made under the statutory grant-in-aid authority of the Public Health Service Act, 42 U.S.C. § 241(c). The grants were made to each of 12 participating university medical centers on the basis of their applications, and a grant was made

[2] 5 U.S.C. § 552(e):

> For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

to the UGDP Coordinating Center at the University of Maryland.[3]

The pertinent background facts are presented in the affidavit of Dr. G. Donald Whedon, Director of NIAMDD:

> 4. The inspiration for the UGDP study came from private non-government physicians and scientists in mid-1959. Between 1959 and 1961, before the study actually began with the entry of the first patients, the design, methods, and objectives of the study were evaluated by persons associated with the UGDP and representatives of NIAMDD. The Food and Drug Administration was not involved in the planning, in-

[3] The institutional grantees are:

Case-Western Reserve University
Cincinnati, Ohio
Greater Baltimore Medical Center
Towson, Maryland
Jewish Hospital and Medical Center of Brooklyn
Brooklyn, New York
Virginia Mason Research Center
Seattle, Washington
Massachusetts General Hospital
Boston, Massachusetts
Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois
University of Alabama
Birmingham, Alabama
University of Cincinnati
Cincinnati, Ohio
University of Maryland
Baltimore, Maryland
University of Minnesota
Minneapolis, Minnesota
University of Puerto Rico
San Juan, Puerto Rico
Washington University of St. Louis
St. Louis, Missouri
West Virginia University
Morgantown, West Virginia

ception, or design of the UGDP study. The study was funded by NIAMDD as part of its responsibility to support research in the field of diabetes and not with any specific regulatory objective in mind.

* * * * *

9. The UGDP raw data (e.g., patient charts and forms) are the property of the individual investigators and the Coordinating Center and are not owned by NIAMDD. Furthermore, it is not the normal practice of NIH or this Institute to require grantees to submit their raw data for review and, in fact, submission of raw data to the institute is extremely rare. Management of the day-to-day operations of grant-supported activities is the responsibility of the grantee. Supervision of the grantee's funded activities by this Institute is generally limited to review of periodic reports submitted by the grantee. (45 CFR §§ 74.80, 74.82). Due to the large number of research grants outstanding—currently approximately 1800—it would not be physically possible for the Institute to subject raw data, if submitted, to critical review, and to require submission of the raw data of the UGDP study would have been an extraordinary requirement. It is the practice to evaluate applications for renewal grants on the basis of progress reports and final reports submitted to NIH. This practice was followed with respect to the UGDP grants. No specific provisions of the UGDP grants required submission of raw data to the Department of Health, Education and Welfare. Pursuant to 45 CFR § 74.23, officers or employees of the Department could obtain access to the raw data for purposes of audit inspection and copying if access is deemed pertinent to the grant. The raw data which are the subject of this case have never been seen by, or been in the possession of, any officer or employee of the National Institutes of Health. * * *

The particular documents sought by the plaintiffs in this case are observations on over 1000 diabetic patients,

who were monitored from 5 to 8 years. It is estimated that there are some 55 million such documents.

In June, 1970, the UGDP investigators made a presentation of the methods and initial results of their study at the annual meeting of the American Diabetes Association. The results indicated that the administration of tolbutamide (an oral hypoglycemic drug) to mild adult-onset diabetics led to a death rate from cardiovascular disease higher than that of groups treated with diet alone, with a fixed dosage of insulin, or with a variable dosage of insulin. The findings were published in the December 1970 Journal of the American Diabetes Association. During 1970 and 1971, over a dozen articles were published in medical journals concerning the study, some supportive and some critical.[4]

The NIAMDD contracted in 1972 with the Biometric Society, a private international professional society of biostatisticians, for an in-depth assessment of the quality of the UGDP study. The Society made a report to the Institute in 1974 that apparently found some merit on both sides of the controversy. It concluded that while some of the criticisms of the UGDP study were valid most were unpersuasive, and the evidence of harmfulness adduced in the UGDP study was "moderately strong." This was made public in the American Medical Association Journal for February 1975.[5]

2. *Food and Drug Administration*

The Food and Drug Administration of HEW, on being apprised of the UGDP results, issued in its October, 1970, Bulletin to the medical community a recommendation that tolbutamide should be used only in cases of adult-onset,

[4] For a listing see 40 Fed. Reg. at 28592.

[5] 131 AMAJ 615.

stable diabetes that could not be controlled by diet and could not be treated with insulin. A June, 1971, FDA bulletin proposed changes in labeling of oral hypoglycemic drugs to warn of cardiovascular hazards. Plaintiff committee sued to enjoin the proposed labeling on ground of deficiencies in the UGDP study, and the First Circuit remanded to the FDA for exhaustion of administrative remedies.[6]

The FDA deferred further action on the labeling pending the review of the UGDP study by the Biometric Society. As already noted, the 1974 report of the Biometric Society was mixed, but overall found "moderately strong" evidence of harmfulness in the UGDP study. Its contract with NIAMDD did not require the Society to seek access to the UGDP raw data, but it apparently did examine some of the raw data.[7] The contract did not require the Society to submit any raw data to the Institute, and none was submitted.

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[6] Bradley v. Weinberger, 483 F.2d 410 (1st Cir. 1973). Plaintiffs contended *inter alia* that prior to regulatory action, the UGDP raw data should be made available to the scientific community. In reversing a preliminary injunction restraining the proposed relabeling, the First Circuit remanded to the FDA, ruling that the underlying questions required review on the full administrative record. Judge Coffin's opinion takes note (p. 414, fn.4) of plaintiffs' contention that the record must include, *inter alia*, the original patient records of the UGDP study, and continues: "While in light of our discussion we need not resolve the propriety of each of these requests, we reiterate what we recently said in an analogous situation: 'We think the law requires production of the entire administrative record . . . where the correctness of factual findings are [sic] involved. . . ."

[7] Plaintiffs say this access was impaired by Society-imposed limitations: to data for only one of the hypoglycemics studied, and only the period prior to October 1969.

3. *FOIA requests and District Court proceedings*

Stressing that the raw data had been made available to the Biometric Society, plaintiffs' committee began a series of FOIA requests in 1974 and 1975 for access to the raw data and a copy of the draft report of the Biometric Society. Plaintiffs were given preliminary galley proofs of the report later published in the AMAJ. HEW notified plaintiffs on August 7, 1975, that the raw data were the property of those engaged in the UGDP study and had not been reviewed or even seen by either the UGDP sponsor (NIAMDD) or FDA.

This FOIA action was begun on September 30, 1975. The complaint sought the production of the raw data, defined as consisting of the forms transmitted to the Coordinating Center and the computer tapes and/or programs on the basis of which the data were analyzed. The complaint also sought a draft report of the Biometric Society.[8]

On Feb. 5, 1976, the district court granted the motion of the HEW officials to dismiss the complaint, on the ground that no official or employee of HEW is now or has ever been in possession of the raw data relating to UGDP, that these raw data are the property of the individual investigators and UGDP study coordinating center, and in the Center's possession, custody and control; that neither the investigators nor the Coordinating Center is an "agency" within 5 U.S.C. § 552, and that the raw data are not "agency records" subject to the disclosure provisions of FOIA.[9]

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[8] It is not clear what draft report is intended, other than the galley proofs already supplied of the subsequently published in February, 1975, see fn.5, above.

[9] The district court dismissed as moot a motion by defendant Dr. Klimt, the director of the UGDP Coordinating Center at the University of Maryland, to quash service of process. Dr.

4. *Developments pending appeal*

On July 25, 1977, while the appeal to this court was pending, Secretary of HEW Califano issued an imminent hazard order suspending new drug applications for phenformin (another oral hypoglycemic drug), and there ensued administrative withdrawal hearings. This court requested supplemental memoranda of the parties on the question of whether data that would become available to plaintiffs as a result of these administrative proceedings would moot the present controversy. The federal appellees put it that there is neither certainty nor likelihood that plaintiffs will obtain access to all the data they seek as a result of the phenformin proceeding. They note, for one thing, that phenformin was only one of the oral hypoglycemic drugs subject to the warning of the UGDP study, the principal one being tolbutamide.

However, it appears that the FDA did examine certain of the underlying raw data (a small portion, quantitatively) in the course of a recent limited audit of the UGDP, and that this portion of the underlying information (except patient-identifying information) has been made available to plaintiff-appellants, and to other interested persons, participating in the phenformin proceeding. The federal appellees' memorandum states: "The FDA has no present intention of obtaining the remaining portions of the UGDP raw data through the auditing rights of the Secretary."

B. Analysis

We rule that the public at large does not have a right under the Freedom of Information Act to the underlying

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Klimt's directorship was based on his position as Director of Clinical Investigation in its School of Medicine. He was represented by the office of the Attorney General of Maryland.

raw data in the hands of the investigators and university groups who conducted the UGDP study program of diabetes under grants from the federal government.

1. The plaintiffs are a respected group of medical specialists asserting that their access to the data would inure to the public interest, by virtue of their concern that the use of drugs they deem valuable may be inhibited. We begin our analysis by observing that in this proceeding under the Freedom of Information Act, the court cannot give any weight to such a consideration.

The only claim ascertainable in this FOIA action is the right of any member of the public, motivated by whatever reasons. The Freedom of Information Act does not depend on a showing of need or interest by the particular applicant for the records. Any showing of need or interest is irrelevant.[10] Such considerations as need, interest, or public interest may bear on the agency's determination of the order of processing applications, but they have no bearing on the substantive right under FOIA to access to the document.[11]

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[10] Sterling Drug, Inc. v. FTC, 146 U.S.App.D.C. 237, 244, 450 F.2d 698, 705; Robles v. EPA, 484 F.2d 843, 847 (1973), repeating the quotation from K. Davis, Administrative Law, 1970 Supp. § 3A.22 (disclosure was never to "depend upon the interest or lack of interest of the party seeking disclosure").

See also K. Davis, id. at § 3A.29: "The Act never takes into account the need of the party seeking the disclosure; it never calls for balancing that need against the interest of a party adversely affected by disclosure. This policy choice reflects pressure from the press that 'the public as a whole has a right to know.' "

[11] It is not relevant under FOIA that the published results of the UGDP were controversial; or that, as plaintiffs allege, the government relied on these results. If the Government examined "UGDP raw data at first hand" (dissent at 10), such data have become agency records and are subject to FOIA. If the Government has relied on results of a study

2. To avoid any possible misunderstanding, we articulate that our ruling embodies no implication as to whether plaintiff physicians will have a right of access to the data underlying the UGDP study in connection with any existing or future actions of the Food and Drug Administration. That issue is distinctly different from what is before us now, and would have to be decided in the light of the record before the FDA.[12]

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based on data that it has not examined, a challenge that this was arbitrary—a matter we do not here decide—may proceed by well-established mechanisms independent of FOIA.

[12] Plaintiffs' memorandum puts it that the First Circuit's opinion impliedly recognizes such a right. While a glimmer of sympathy for plaintiffs' position may be extracted from a reference in that opinion, tucked away in a discreet footnote, all that is said by the court is that the case in court must be determined on the basis of the entire administrative record. The issue here is whether the data in the hands of the researchers are part of the agency's records.

The issue of fairness to plaintiffs will require attentive consideration in the light of the administrative record. When issues of risk of harm are involved, an agency may use results of scientific researchers even without access to underlying data, as is evidenced by the frequent use of foreign studies, *see e.g.*, Ethyl Corp. v. EPA, 176 U.S.App.D.C. 373, 400, 541 F.2d 1, 28 (en banc), *cert. denied*, 426 U.S. 941 (1976). In the present case the government has undertaken some audit review of the raw data. Plaintiffs' memorandum argues that this audit was subject to limitations that undercut its utility, but obviously we cannot appraise that issue on the record before us at this time. A court reviewing the situation on the entire administrative record would also take into account the appraisal of the Biometric Society. We cannot on our record appraise its work and its significance, let alone either plaintiffs' aspersions on the way in which that Society's committee conducted itself or the government comment that its membership embraced a wide span of scientific opinion.

The Biometric Society set forth flaws in the work of the UGDP investigators, but when an investigation requires a protracted period flaws are not wholly unexpected, and their

The FDA and NIAMDD are both in HEW, but that department is a conglomerate that embraces many and distinctly different activities. Insofar as it is engaged, through FDA, in a regulatory program, it may be subject to requirements of revelation that go beyond the FOIA's rules that govern all agencies. The FDA's regulatory actions are not before us in this FOIA lawsuit, which focuses on whether data become HEW records by virtue of study and granting activities (of NIAMDD).

3. This action requires that the persons invoking the FOIA show that they seek "agency records." The NIAMDD is a government agency, of course. But the persons or institutions who receive study grants from that Institute, or indeed from any branch of the federal government, do not on that account become government agencies.

To some extent, our path is lighted by *United States v. Orleans*, 425 U.S. 807 (1976). The case involved the Warren-Trumble council, a community action agency operating as a non-profit corporation under Ohio law, that was funded entirely by a federal agency, the Office of Economic Opportunity. Under the Economic Opportunity Act of 1964, the OEO furnished financial assistance to a community action agency, in turn defined as one designated by the state to plan and administer a community action program of "services and activities having a measurable and potentially major impact on causes of poverty in the community." The issue was whether or not one of the activities of the Ohio community action agency, the sponsoring of recreational out-

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appearance may still leave the study with utility for appraisal of risk of harm to the public. *See* Certified Color Manufacturers Assoc. v. Mathews, 177 U.S.App.D.C. 137, 543 F.2d 284 (1976). The reviewing court would also consider the reasons, if any, given in any FDA proceeding involving oral hypoglycemic drugs for denying participants access to the raw data.

ings for children, if conducted negligently, could give rise to an action under the Federal Tort Claims Act. The Supreme Court held that it could not, since the council was not a federal agency or instrumentality, and its employees not federal employees. The Court found that a critical element in distinguishing a federal "agency" from either a contractor with the federal government or a grantee of the federal government, was the federal government's "control [of] the detailed physical performance." [13]

Ou decision today is congruent with our decision in *Washington Research Project v. HEW*, 164 U.S.App.D.C. 169, 504 F.2d 238 (1974), which reversed a district court order granting disclosure of certain reports made to the National Institute of Mental Health, a unit of the Public Health Service of HEW. The case involved reports made, on applications for research support, by peer review groups ("initial review groups" or IRG). The IRG peer review system was established by the government to assure competent evaluation of proposals through the use of "expertise of nongovernmental consultants functioning in panels organized around particular specialized disciplines within the broader field of biomedicine." [14]

[13] At fn. 5, 425 U.S. at 816, the Court put it that the issue was whether "there was day to day control of a program," it being irrelevant whether the program was funded by means of a contract or grant. The Court stressed (425 U.S. at 815): "Billions of dollars of federal money are spent each year on projects formed by people and institutions . . . responsible to the United States for compliance with the specifications of a contract or grant, but they are largely free to select the means of its implementation." The Court found it irrelevant that the local council did not obtain funds from any other sources or conduct any programs without federal money (425 U.S. at 818 n.7).

[14] 504 F.2d at 242.

The reports sought included a "site visit" to observe the pertinent experimental technique, and a "summary statement" of the observations and deliberations of the group, prepared by a NIMH staff member assigned to assist the group. The legal issue focused on whether the initial review group was itself a government "agency," in which case its own reports would be "final opinions" required to be disclosed under FOIA, and not intra-agency memoranda excluded under exemption 5. Acknowledging the "myriad organizational arrangements for getting the business of the government done," [15] the court concluded that "the IRG's are advisory committees, performing staff functions through the medium of outside consultancy, and are not agencies." [16] It observed, significantly, "Employing consultants to improve the quality of the work that is done cannot elevate the consultants to the status of the agency for which they work unless they become the functional equivalent of the agency, making its decisions for it." [17]

4. Plaintiffs seek to avoid a head-on contention that federal grantees be assimilated as federal agencies. Instead they emphasize a congeries of considerations that they think cumulate to a right of public access to documents in the hands of the grantees.

[15] 504 F.2d at 246.

[16] 504 F.2d at 246.

[17] 504 F.2d at 248. Such consultants are employed and paid under the Public Health Service Act, 42 U.S.C. §§ 210, 217a. The court acknowledged that the consultant group's recommendations were undoubtedly "an often crucial element" in the approval process of the government, which was often typically a "perfunctory review." It regarded the degree of scrutiny as irrelevant to the court's consideration, stating that the fact that the government "may be greatly influenced by the IRG's expert view does not make the IRG an agency."

In addition to the responsibility of plaintiffs and a claim of public interest in their access, which we have already shown to be irrelevant, plaintiffs stress the following: This was a multi-million dollar study, entirely funded by the federal government, of such a scale as to be non-replicable by private efforts and a unique public resource. By contract and regulation, the raw data underlying the study are available for government review, copying and storage. The government's exercise of its rights of audit demonstrates its "complete dominion and control" over the data through the audit process.

The Institute's grant documents establish its right of access to "any books, documents, papers, and records of the grantees" for certain purposes. To the extent that the language of the grant is material, it indicates that these are not agency records prior to the exercise of that right.

Plaintiffs' claim is in effect an assertion that the federal government should be required—formally or constructively—to exercise its contract-grant right of access in order to provide general public access. We cannot accept this proposition. The Freedom of Information Act only gives a right of access to agency records in existence. It does not confer a right to have the government generate agency records, either by creation, subpoena or contract demand. That conclusion is implicit in *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975). The Court there granted the public a right to the production of the agency's appeal memorandum, pursuant to its understanding that the Act "represents a strong congressional aversion to 'secret [agency] law.'" (421 U.S. at 153). However the Court held that the public had no right to a judicial requirement that the agency produce or create explanatory material in the case of an appeals memorandum that referred only conclusorily to the "circumstances of the case." See 421 U.S. at 161:

> The Act does not compel agencies to write opinions in cases in which they would not otherwise be required to do so. It only requires disclosure of certain documents which the law requires the agency to prepare or which the agency has decided for its own reasons to create.

The governing principle is that only if a federal agency has created or obtained a record (or has a duty to obtain the record)[18] in the course of doing its work, is there an agency record that can be demanded under FOIA.[19]

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[18] Judge MacKinnon's opinion leads me to acknowledge that this parenthetical reference is, strictly speaking, dictum. Yet in rejecting the claim that there is an FOIA entitlement because of the *power* of the agency to obtain a record, it seems material to observe that I see a distinction where the agency has the *duty* to obtain the record. In that instance, I do not conceive that the official may lawfully resist the claim for the document on the ground that he has chosen to violate his official duty (to obtain it). In legal terms, the claim and lawsuit are in effect a joinder of two requests, and a joinder of an action in mandamus with one under the Freedom of Information Act.

[19] We do not suggest that mere physical possession of records by a government agency is the sole criterion for determining whether they fall within the scope of FOIA. Obviously a government agency cannot circumvent FOIA by transferring physical possession of its records to a warehouse or like bailee.

Where records are created by a private entity, we believe the applicability of FOIA will turn on whether the government is involved in the core planning or execution of the program, or whether, by contrast, the entity retains its private character in bona fide fashion during the course of the endeavor that results in the records. Even in the latter situation, however, records that are examined by the government through audit rights may become agency records under FOIA—if, for example, the records are copied by the agency or come into its possession.

5. Overarching policy considerations are stressed by physician applicants. There is a plea for liberal reading of reform legislation. We agree that this reform legislation should not be niggardly construed in contravention of legislative objective. The "basic thrust" of the Act embraces "a general philosophy of full agency disclosure" subject to specific exemptions and the objective "to pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny." [20]

However, the general policy of avoiding agency secrecy does not give a charter for extending the law beyond the domain of "agency" and "agency records" that is the keystone of the Act. To stretch for data in the possession of federal grantees, cannot be justified as within the fair contemplation of Congress either at the time the law was passed or amended, or even today under a doctrine of trying to reconstruct specific legislative intent in the light of the broad purposes disclosed by Congress.[21]

It is tautology to say that requiring disclosure of grantee records will promote the disclosure policies of FOIA. But disclosure is not required by the statute unless those records are agency records. Congress struck a balance in fashioning the FOIA, which precludes the boundless pursuit of one policy goal, even a dominant policy, to the exclusion of all countervailing considerations.

If the statute is to be given the kind of interpretation sought by plaintiff physicians, the impact would be

[20] Department of Air Force v. Rose, 425 U.S. 352, 360 (1976). Opinions of this court to the same effect include Bristol Myers Co. v. FTC, 138 U.S.App.D.C. 22, 25, 424 F.2d 935, 938 (1970); Getman v. NLRB, 146 U.S.App.D.C. 209, 211, 450 F.2d 670, 672 (1971).

[21] Montana Power Co. v. FPC, 144 U.S.App.D.C. 263, 445 F.2d 739 (1970), *cert. denied*, 400 U.S. 1013 (1971).

far-reaching. The number of documents in any one study would be stupendous—reaching millions in the single case before us. The number of federal grants and contracts is not a matter of record, but as was noted in *Orleans*, they account annually for disbursements in the billions. The awesome implications of plaintiffs' contention cannot be shrugged off because modern technology permits access to documents on tape through computer printouts, without need for physical production.

Scientists engaged in research on federal grants must accept the fact that any documents filed with the federal government, whether on the scientists' own initiative or an audit or other lawful demand, are subject to FOIA. Even in scientific terms, any such audit provides a surrogate for the kind of reliability usually accorded to scientific studies by replication of experiments when feasible. However, an undertaking to be audited by responsible personnel is not the same as an agreement to accept rummaging by the world at large.

The court will not trim FOIA by speculation as to adverse motivation or reaction of the scientists.[22] Similarly, the court cannot supply the extension of the reach of the Act sought by plaintiffs by building on a policy speculation that such an extension would not throttle scientific cooperation and research. This involves matters beyond our proper sphere of judicial notice.

What is requested in this action, in our view, is an extension of the statute on claim of public interest that

[22] In considering Exemption 4 for trade secrets or commercial information, the court found it irrelevant to inquire whether non-commercial scientists are either "a mean-spirited lot who pursue self-interest as ruthlessly as the Barbary pirates did in their own chosen field," or are governed by the loftier consideration that "secrecy is antithetical to the philosophical values of science." Washington Research Proj., Inc. v. HEW, 164 U.S.App.D.C. 169, 175, 504 F.2d 238, 244 (1974).

must be appraised by the legislature which can give the subject extended study, elicit opinions from all interested sources, and consider the pro's and con's.

6. It is fitting to close by referring to the need, in any pondering of such extension of the FOIA, for considering the impact on the philosophy and purpose of Federal grant programs.

Grant programs represent a means for the governance of our society which is rooted in a pluralistic conception of the value of drawing on both private and governmental sources. A leading student of Federal grant law puts it [23]

> The grant is assistance to an autonomous grantee. The grantee is not an arm, agent or instrumentality of the grantor. The employees of the grantee are not federal employees. The torts of the grantee are not federal torts. The property of the grantee is not federal property.

The reference to "an *autonomous* grantee" is a core concept, not an incidental observation. In a grant program the federal government gets the advantage of services rendered by someone who is doing his own thing, his own autonomous thing. It is not the same as a government operation in disguise.

Through its grants to university groups, the government obtains the efforts of creative persons who flourish in an academic atmosphere. Such arrangements provide a measure of detachment and independence from the mission of the government agency. The researchers may feel the tug of government purse strings, but they also feel answerable to the standards of their academic colleagues.

Plaintiffs cite the multi-million dollar nature of the study as a reason for access. There is at least a question whether the federal government could have conducted directly, through its own employees and resources, a study program so long in time, so broad in space, and covering so many patients and controls. Even in a case where the grant is to conduct a study that might conceivably be conducted by federal employees, there is an advantage in terms of effective government and advancement of the public interest if the study is done by various institutions. The government goes beyond the capabilities of its own employees, adding the spirit and insights of the scientists and students who have selected a different life style, at a center of learning.

[23] M.S. Mason, *Current Trends in Federal Grant Law-Fiscal Year 1976*, 35 FED BAR 163, 167-68 (1976).

As earlier noted, we are not concerned here with the kind of case where the federal government exercises detailed control over operations. Such a condition presents different considerations, as noted in *Orleans*. Nor do we have a suggestion of subterfuge, with a federal agency seeking to conduct research outside the scrutiny of government laws, by using facilities that are independent only nominally. The case before us concerns a UGDP study conceived in 1959 by private, non-government physicians and scientists. They developed their own methodology; it was not dictated by the federal government.

Of course, in any program funded by the federal government there is an opportunity for the government to assess the results of the performance and of any studies. There may also be directions by the federal government in certain matters of public policy that are essentially peripheral to the core of the work done. There may, for example, be a requirement of avoidance of discrimination on grounds of race, religion, creed or sex. There may be achievement of other government objectives which apply across the board to all activities financed by the federal government.

The central question is whether the government is really involved in the core of the program. At least in a case such as the one before us, where there was no claim of significant government control of day-by-day operation, or detailed involvement in the planning or execution of the program, the overall concept of autonomy of grantees persists, even though there are federal objectives, right of federal audit and perhaps some overarching federal requirements.

At least a fleeting reference should be made to acknowledge that some of the federal grantees are institutions of the state governments.[24] There are thus considerations of federalism involved. These are not necessarily of constitutional dimension. However, they are not without relevance in appraising the extent to which such grantees are automatically governed by rules provided by Congress for the federal agencies, such as govern access to records and meetings, or personnel management,[25] or any other rules.

The foregoing matters indicate that a balance must be struck, one that considers the advantages of grantees that are autonomous and have value because they are not governmental, and the possibly conflicting policy that cherishes full and free public access to government agencies and shuns secrecy as invidious. Such a balancing is a task for the legislature. The extension of access sought by plaintiffs on the ground of public interest is not properly addressed to the courts.

Affirmed.

[24] See note 9, *supra*, as to University of Maryland.

[25] National League of Cities v. Usery, 426 U.S. 833 (1976).

MACKINNON, *Circuit Judge*, concurring: I join generally in Judge Leventhal's opinion but wish to add the following observations.

5 U.S.C. § 552(a)(3) provides: "[E]ach agency, upon any request for *records* . . . shall make the records promptly available to any person." 5 U.S.C. § 552(a)(4)(B) also refers to the location of "*agency records*" as constituting one basis for conferring on the district court for that district "jurisdiction to enjoin the agency from withholding *agency records* and to order the production of any *agency records* improperly withheld from the complaint. In such a case the court . . . may examine the contents of such *agency records* in camera . . . ." (Emphasis added.) A fair conclusion from the foregoing indicates that it is not just "records" but "*agency* records" that the statute is addressing.

The court's opinion at page 16 states:

> The governing principle is that only if a federal agency has obtained a record (*or has a duty to obtain the record*) in the course of doing its work, is there an agency record that can be demanded under FOIA. [Emphasis added.]

The italicized statement is not necessary to our decision and I do not join in it. Each particular case involving a request for records not in the possession of an agency but for which, it is alleged, there is some duty to obtain the records must be decided on its particular circumstances. I would leave to a future opinion any declaration as to the extent to which FOIA should be interpreted to cover records not created by, obtained by, or otherwise in the possession of an agency. The plain implication derived from the language of the statute is that it does apply to records which belong to the agency or are in its possession—that is, records which the agency has created or obtained. That is all that is needed to decide

this case. I would not refer to records about which it might be said that an agency might have some duty to obtain until such time as we are presented with a case that raises the question directly and presents to us all the relevant facts necessary to decide the applicability of FOIA to that situation.

The dissent would go even further and substitute for the normal interpretation of the language of the statute a meaning to be derived from an extraneous examination of "*all* the relevant circumstances surrounding the creation, preservation, and use of [the] particular records" (Dissent at 6, emphasis original). Then, "[i]f this analysis reveals a significant degree of federal involvement with the records, then they should be considered agency 'records' subject to FOIA" (*Id.*, footnote omitted). The *catch* is allowing the interpretation of the statute to turn upon what a judge might consider a "*significant* degree of federal involvement." The attempt is to impose a "chancellor's foot" standard which varies with each judge. The statute, however, is not susceptible of such construction, and happily so, for those whose foot gives them a short standard would find records to be "*agency* records" wherever there was any federal funding or access to the records. That standard, as applied by some courts, would extend FOIA to practically unlimited lengths in those universities and industries which engage in private research. If Congress desires the Act to be so extended, it can do so by enacting appropriate legislation; but my view coincides with that expressed in Judge Leventhal's opinion, that such an extreme extension of the Act should not be created by judicial fiat.

In reaching this conclusion, I see no harm to the public. Where particular records are the subject of legitimate inquiry, as in the two cases referred to in the dissent, they may be subpoenaed by interested parties.

BAZELON, *Circuit Judge, dissenting*: Plaintiffs seek disclosure of the raw data of a federally-sponsored research project, the University Group Diabetes Program (UGDP). The UGDP data are locked in a bank vault in Maryland in the custody of the UGDP program coordinator. For the majority, this means they are not agency "records" subject to disclosure under the Freedom of Information Act (FOIA). With all due respect, I cannot agree.

In my view, factors other than possession are relevant in determining whether the UGDP data are agency "records." The Federal Government has provided all of the funding for the UGDP; the Government has an unrestricted right of access to the data; and importantly, the Government has extensively relied on the UGDP study and data in regulatory action affecting the treatment of diabetes. I think these factors cumulatively establish a significant degree of federal involvement with the UGDP raw data. Accordingly, I would hold that they are agency "records."

I.

The Freedom of Information Act requires federal agencies to disclose all "records," 5 U.S.C. § 552(a)(3),[1] that

[1] [E]ach agency, upon request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

5 U.S.C. § 552(a)(3) (1974). As originally enacted, this section provided:

> [E]ach agency, on request for identifiable records made in accordance with published rules stating the time, place, fees to the extent authorized by statute, and procedure to be followed, shall make the records promptly available to any person.

[Continued]

do not fall within one of nine exemptions. *Id.* § 552(b)(1)-(9). No definition of the term "records" is found in either the Act or the legislative history.[2] The case law, focusing almost exclusively on the exemptions, sheds little light on this term.[3] We are thus left with little

[1] [Continued]
The section was amended in 1974 to make clear that "[a] 'description' of a requested document would be sufficient if it enabled a professional employee of the agency who was familiar with the subject area of the request to locate the record with a reasonable amount of effort." H.R. REP. No. 876, 93d Cong., 2d Sess. 5-6 (1974).

[2] The 1967 Attorney General's Memorandum does contain one sentence relevant to the definition of agency records. It says: "Subsection (c) [552(a)(3)] refers, of course, only to records in being and in the possession *or control* of an agency." R. Clark, Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act (1967) *reprinted in* Freedom of Information Act Source Book, S. REP. No. 82, 93d Cong., 2d Sess. 222 (1974) (emphasis added). Although the Attorney General's Memorandum is a doubtful guide to congressional intent, see K. DAVIS, ADMINISTRATIVE LAW TREATISE 117 (1970 Supp.), the fact that it refers to two criteria for defining agency "records"—possession or control—suggests a more inclusive approach than that adopted by the majority. I would also argue that the Attorney General's Memorandum is consistent with the result I would reach here, since in my view the Government involvement with the UGDP data amounts to "control."

[3] *But see* Goland & Skidmore v. CIA, No. 76-1800 (D.C. Cir., May 23, 1978) (congressional hearing transcript in possession of agency not an agency record); SDC Development Corp. v. Mathews, 542 F.2d 1116 (9th Cir. 1976) (materials in medical reference library not agency records); Cook v. Willingham, 400 F.2d 885 (10th Cir. 1968) (per curiam) (presentence report in the hands of prison authority not an agency record); Ciba-Geigy Corp. v. Mathews, 428 F. Supp. 523 (S.D. N.Y. 1977) (UGDP raw data not agency records); Nichols v. United States, 325 F. Supp. 130 (D. Kan. 1971), *aff'd*, 460 F.2d 671 (10th Cir.), *cert. denied*, 409 U.S. 966 (1972) (physical evidence relating to assassination of President Ken-

direct guidance in attempting to elucidate a key provision of the Act.

The majority does not discuss the difficulties involved in defining agency "records." It simply asserts, with little supporting rationale, that the crucial question is whether the documents have been "created" or "obtained" by a federal agency.[4] In adopting this approach, the majority joins with the federal defendants and the district court in looking to such factors as property rights and possession in defining agency "records."[5] I have no

nedy not "records"). I exclude cases that turn on the definition of a federal "agency." *E.g.*, Soucie v. David, 448 F.2d 1067 (D.C. Cir. 1971).

[4] Maj. op. at 16. Apparently, the majority would also recognize agency "records" where the Government is involved in the "core planning or execution" of a program, maj. op. at 16 n. 19, 21; and where a federal agency has a duty to obtain records. Maj. op. at 16. *But see* concurring op. at 1.

[5] The district court found that

> (1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institute of Health (NIH), the Food and Drug Administration (FDA), or the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) . . .; (2) the raw data in question is [sic] the property of the individual investigators and UGDP coordinating center and remains in the possession, custody and control of the UGDP study coordinating center. . .; (3) neither the individual investigators nor the UGDP study coordinator is an 'agency' within the purview of the Freedom of Information Act, 5 U.S.C. § 552; and (4) consequently, the raw data in issue are not 'agency records' subject to the disclosure provisions of the Freedom of Information Act, 5 U.S.C. § 552(B).

Joint Appendix (J.A.) at 146-47 (footnote omitted).

[Continued]

objection to title or custody as relevant criteria. I do object, however, to a test based on only some of many possibly relevant factors, with little justification offered for the primacy of these factors. The place to start in determining the scope of agency "records" is not with assertion, but with an examination of the policies of the FOIA.

There can be no doubt about the basic goals of the Freedom of Information Act. As the Senate Report put it, the fundamental premise of the Act is that "the public as a whole has a right to know what its Government is doing." S. REP.NO. 813, 89th Cong., 1st Sess. 5 (1965). FOIA was designed, in the words of the Report, "to establish a general policy of full agency disclosure unless information is exempted under clearly delineated statutory language. . . ." *Id.* at 3. In the House, Congressman after Congressman rose to speak in suport of the policy underlying the bill. This was, as they variously put it, the right to the public "to information relating to the actions and policies of Federal agencies," 112 CONG.REC. 13655 (1966) (remarks of Rep. Hall); "to know the facts about the operation of their government," *id.* at 13657 (remarks of Rep. Reid); "to be fully informed about the policies and activities of the Federal Government," *id.* at 13648 (remarks of Rep. Faschell). These statements suggest the need for a broad definition of agency "records": broad enough to let the public know everything "its Government is doing;" to illuminate all "policies and activities of the Federal Government."

[5] [Continued]

The federal defendants' position is that "the term 'agency records' in the Freedom of Information Act applies to 'records' in the possession of a federal agency or owned by an agency, or produced under the day-to-day supervision of an agency." Gov. Br. at 17.

The principle that "the disclosure requirement be construed broadly. . . ," *Soucie v. David*, 448 F.2d 1067, 1080 (D.C.Cir. 1971), is also rooted in the structure of FOIA. Before FOIA was enacted, the public information section of the Administrative Procedure Act allowed agencies to withhold information "in the public interest," or "for good cause shown," or if the person seeking the information was not "properly and directly concerned." 5 U.S.C. § 1002 (1964). These broad exemptions created what was in effect a "withholding statute," not a "disclosure statute."[6] To remedy this situation, Congress enacted a statute containing a general disclosure section and nine narrowly drawn exemptions. The disclosure section provided that "any person" could have access to any agency "record," without having to state a reason for wanting the information. And the exemptions were drafted to provide "definitive guidelines"[7] as to what information could be withheld. To avoid new loopholes, Congress expressly limited the grounds for nondisclosure to those specified in the exemptions.[8] The objective was to "make it clear beyond doubt

[6] S. REP. No. 813, *supra* at 5.

[7] *Id.* at 3.

[8] This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section.

5 U.S.C. § 552(c) (1970).

I agree that in enacting FOIA Congress struck a deliberate balance between a policy of full disclosure and various countervailing policies. Maj. op. at 17. But the legislative history makes it abundantly clear that all of the competing policies *Congress* saw fit to recognize were to be accommodated through nine specific exemptions. It comes as a surprise, therefore, to learn that a policy not mentioned by Congress—that of preserving grantee "autonomy," maj. op. at 19 is to be realized through a restrictive definition of agency "records."

that all *materials of the Government* are to be made available to the public by publication or otherwise unless explicitly allowed to be kept secret by one of the exemptions in [§ 552(b)]." S.REP.No. 813, *supra* at 10 (emphasis added in part).

Both the purpose and the structure of FOIA point to a broadly inclusive definition of agency "records"—a definition encompassing "all materials of the Government." I seriously doubt that common law notions of property or custody can define the totality of such records. In my view, the appropriate approach under the statute is to examine *all* the relevant circumstances surrounding the creation, preservation, and use of particular records. If this analysis reveals a significant degree of federal involvement with the records,[9] then they should be considered agency "records" subject to FOIA.

II.

Plaintiffs emphasize three forms of federal involvement with the UGDP research data: federal funding of the data, federal access to the data, and federal reliance on the data in administrative decisionmaking. We need not decide whether one of these factors, or even two of these factors in combination, would be sufficient to make the

[9] Another court that has grappled with whether the UGDP raw data are agency "records" concluded "that the goals and purposes of the Act would be served best by imposing a standard which calls for proof that the records were either Government-owned or subject to substantial Government control or use. In other words, it must appear that there was significant Government involvement with the records themselves in order to deem them agency records." Ciba-Geigy Corp. v. Mathews, 428 F. Supp. 523, 529 (S.D. N.Y. 1977). Although I disagree with Judge Tenney's application of this standard, particularly his conclusion that the Government has not directly relied on the UGDP raw data, *id.* at 531, I have no quarrel with his statement of the standard itself.

UGDP data agency "records." Where all three factors are present, however, I think these materials are clearly agency "records."

A. *Government Funding*

One hundred percent of the UGDP funding was provided by the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), one of the institutes of the National Institutes of Health. Federal funding is significant for FOIA purposes for two reasons. First, funding of scientific research is a federal activity, and FOIA was enacted to allow the public to obtain information about all federal activities—including the expenditure of money. As one Congressman put it, FOIA was intended in part to enhance the rights and responsibilities of the voting public by making it possible for them to know "what their Government is doing with their money." 112 CONG.REC. 13659 (1966) (remarks of Rep. Gurney); *accord* 110 CONG.REC. 17088 (1964) (remarks of Sen. Dirksen).

Federal funding of the UGDP is also important because funding brings with it significant Government control over the use, maintenance, and disposition of the UGDP raw data. This can be seen by examining HEW regulations governing the relationship between the Government and the grant recipient. Under these regulations, the grantee is obliged to retain "financial records, supporting documents, statistical records, and all other records pertinent to an HEW grant" for a period of three years after receiving the grant. 42 C.F.R. § 74.20. If the granting agency determines that any of the records generated by the grantee have "long term retention value," the agency may order the records transferred to the Government for permanent custody. *Id.* § 74.20(b). At all times, the Government has the right of access to "any books, documents, papers, and records of the grantee"

for the purpose of making "audit, examination, excerpts and transcripts." *Id.* § 74.23(a). The regulations further require that the grantee retain all "[l]aboratory notes, related technical data and information" that pertain to a patentable invention, and make them available to HEW upon request. *Id.* § 52.22. And if the grantee copyrights a publication resulting from the grant, the regulations give the Government a royalty free, nonexclusive license "to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so." *Id.* § 52.23. While these provisions probably fall short of establishing full federal ownership of the UGDP data, *see* Gov. Br. at 26-31, they do establish, I think, that the Government has a substantial degree of control over the use and disposition of the UGDP records.

B. *Government Access*

Under the HEW grant regulations, the Government has an apparently unlimited right of access to the UGDP raw data. 45 C.F.R. § 74.23(a) provides:

> HEW and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the grantee which any of them determine are pertinent to a specific HEW grant, for the purpose of making audit, examination, excerpts and transcripts.[10]

[10] The Government may have access to the UGDP raw data under FDA regulations as well. 21 C.F.R. § 312.1(a)(12)(6)(e) gives the FDA the right of access to investigator's records relating to investigational new drugs (INDs). The UGDP holds two INDs from the FDA. J.A. at 92. The federal defendants note that the regulation requires investigators to *retain* such records for only two years after administration of an IND has been discontinued, and assert that the UGDP discontinued use of its INDs more than two years ago. Gov. Br. at 34-35. However, there is no indication that the UGDP has in fact discarded the records, or that the FDA *right of access* is extinguished two years after administration of an IND stops.

HEW is permitted to "examine" and "excerpt" not only the financial records of the UGDP, but also raw research records. This is demonstrated by the fact that when the FDA conducted a scientific audit of the UGDP, portions of the raw data were examined by government investigators, copied, and then retained by the agency. Gov. Supp. Memo. of Dec. 5, 1977.

The Government's right of access to the UGDP raw data is important for FOIA purposes since it establishes the basis for Government compliance with FOIA requests. Obviously, the Government must be able to obtain copies of requested agency "records" quickly and without legal impediment.[11] For example, if the Government had to purchase certain data, or subpoena certain records to comply with a FOIA request, these materials might not be considered agency "records." We need not decide this question, for no such barrier is involved here. The Government can exercise its right of access to the UGDP data at any time and for any reason. To be sure, greater inconvenience may be involved in obtaining copies of documents not in the immediate custody of the agency. But, as the Government concedes, agency "records" need not be located within the physical confines of the agency.

[11] The Act requires agencies to determine whether to comply with a FOIA request "within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request. . . ." 5 U.S.C. § 552(a)(6)(A) (1974). An additional 10 days is permitted in "unusual circumstances," including "(i) the need to search for and collect the requested records from field facilities or *other establishments* that are separate from the office processing the request; . . ." *Id.* § 552(a)(6)(B)(i) (emphasis added). The last provision appears to specifically contemplate that agency "records" can be found outside the custody of the agency.

Gov. Br. at 20 n.32. Records may be bailed to a privately-owned warehouse, loaned to a private entity, or may have been sold or donated to the Government but not delivered. In terms of ease of compliance with FOIA, these types of situations are indistinguishable from the present case.[12]

C. *Government Reliance*

Probably the strongest link between the UGDP data and the Federal Government is found in the extensive history of federal reliance on the UGDP study and data in regulatory action dealing with the treatment of diabetes. This reliance must be viewed against the background of intense controversy surrounding the UGDP ever since the study's first conclusions were published in 1970.[13]

[12] The majority's assertion that NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 161-62 (1975) and Renegotiation Board v. Grumman Aircraft Engineering Corp., 421 U.S. 168, 192 (1975) require more than a mere right of access to documents is without foundation. These cases stand only for the proposition that FOIA does not oblige an agency to *write* opinions. They say nothing about the duty to retrieve records that are reasonably described, admittedly exist, and are within an agency's power to obtain.

[13] Klimt, Knatterud, Meinert & Prout, *The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes*, 19 DIABETES (Supp. 2) 747 (1970). Subsequent reports were published in Knatterud, Meinert, Klimt, Osborne & Martin, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: IV. A Preliminary Report on Phenformin Results*, 217 JAMA 777 (1971); Goldner, Knatterud & Prout, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: III. Clinical Implications of UGDP Results*, 218 JAMA 1400 (1971); Knatterud, Klimt, Osborne, Meinert, Martin & Hawkins, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: V. Evaluation of Phenformin Therapy*, 24 DIABETES (Supp. 1) 65 (1975).

Release of the UGDP's initial findings, suggesting a possible correlation between oral hypoglycemic drugs and cardiovascular mortality, had a profound impact.[14] Professional conferences were convened, articles were published, and scientific studies were undertaken with the hope of evaluating the UGDP conclusions and determining their validity. The medical and scientific communities eventually divided along pro- and anti-UGDP lines. Supporters of the UGDP cited the study's cost, duration, broad patient base, and sophisticated design as confirming the validity of the findings.[15] Critics of the UGDP, on the other hand, pointed to alleged inadequacies in study design, methodology, and execution.[16] The controversy was compounded when a UGDP investigator, Dr. Angela Bowen, resigned from the study, challenging the integrity of the program director and suggesting a possible manipulation of the data base to reach results unfavorable to one of the drugs under study.[17]

[14] Some of the controversy surrounding the UGDP study is reviewed in the majority opinion at 3-7.

[15] *See, e.g.*, Cornfield, *The University Group Diabetes Program: A Further Statistical Analysis of the Mortality Findings*, 217 JAMA 1676 (1971); Prout, Knatterud, Meinert & Klimt, *The UGDP Controversy: Clinical Trials Versus Clinical Impressions*, 21 DIABETES 1035 (1972).

[16] *See, e.g.*, Feinstein, *Clinical Biostatistics: An Analytical Appraisal of the University Group Diabetes Program (UGDP) Study*, 12 CLIN. PHARMACOLOGY, THERAPEUTICS 167 (1971). Schor, *The University Group Diabetes Program: A Statistician Looks at the Mortality Results*, 217 JAMA 1671 (1971).

[17] Dr. Bowen testified as follows before FDA at the public hearings on the proposed labeling change for oral hypoglycemic drugs:

> An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has

Despite all the uncertainty about the validity of the UGDP study, and the inability of sceptical scientists and physicians to examine the raw data, the Federal Government has twice relied on the UGDP findings in regulatory action affecting a large segment of the public. In

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also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "were the data that were gathered in the field accurately and honestly recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or other side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. [Tolbutamide is an oral hypoglycemic drug and a competitor of phenformin.] It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstances was discussed at length. This ended with the demand from the New York delegation that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfield and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators.

J.A. at 130-31.

1975, the Commissioner of the Food and Drug Administration (FDA) proposed new labeling requirements for oral hypoglycemic drugs used in the treatment of diabetes. 40 FED.REG. 28587 (1975). The *Federal Register* notice of the proposed warning stated in part:

> The judgment of the Commissioner that changes must be made in the labeling of the oral hypoglycemic drugs to reflect the findings of the UGDP study is well known. . . .
>
> The warning proposed in this labeling is based primarily on a thorough review and evaluation of the UGDP study. . . .
>
> The Commissioner reaffirms his view that the UGDP study is an adequate and well-controlled clinical trial, which is the most extensive and detailed examination of the long-term administration of hypoglycemic agents yet undertaken.
>
> . . . The Commissioner believes that the UGDP study is a validly conducted trial and accepts the opinion of the Biometric Society committee and other experts that the increased cardiovascular mortality found in this trial cannot reasonably be attributed to scientific shortcomings in the study.

Id. at 28591.[18] A clearer affirmation and reliance on the UGDP study is hard to imagine.

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[18] The Commissioner of FDA recognized that "[f]rom the time the results of the UGDP study were first reported, the study was subjected to intense criticism by both clinicians and statisticians." 40 FED. REG. 28588. He conceded that "a wide-spread belief had developed among many physicians that the UGDP study was somehow flawed in terms of its design and execution, and therefore could not serve as a proper basis for a warning to the medical profession." *Id.*

> The agency therefore decided to postpone implementation of the warning until [review of the UGDP study by

Later, in 1977, Secretary Califano of HEW declared phenformin, an oral hypoglycemic drug, an "imminent hazard to public health" under § 505(e) of the Food and Drug Act, 21 U.S.C. § 355(e), and suspended approval of all new drug applications for this drug. The Secretary indicated that he was relying to a considerable extent on the statistical evidence gathered by the UGDP. The order stated that "[t]he FDA, which is experienced in interpreting and aanlyzing incidence figures for adverse reactions, has examined [the UGDP] statistics and concluded that the incidence figures are scientifically valid."

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a committee of the Biometrics Society] was published. Since the UGDP study was the basis for the proposed warning, the Commissioner believed that this independent review of the statistical validity of the study should be available to all interested persons before taking definitive action. The review by the committee of the Biometrics Society required extensive reanalysis of the data in the UGDP study and was not published until February 10, 1975.

Id. at 28589.

The Biometrics Society audit reconfirmed the Commissioner's belief in the need for regulatory action based on the UGDP.

> Although the [UGDP] has shortcomings, which might be expected in any clinical trial of this complexity, the shortcomings do not invalidate the central finding that there appears to be an increased risk of cardiovascular mortality associated with the administration of tolbutamide and of phenformin to maturity-onset diabetic patients, compared to treatment with diet alone or diet plus insulin. This conclusion has in the past been reached independently by the UGDP investigators, the FDA, and the Biometrics Society committee, and is again affirmed by the Commissioner. Other clinical trials of these oral hypoglycemic drugs are not comparable to the UGDP study and provide insufficient evidence to negate the findings of the UGDP study.

Id. at 28591.

Order of the Secretary Suspending Approval at 11 (July 25, 1977).[19]

Significantly, the proposed labeling change and suspension of phenformin were not undertaken solely on the basis of the published studies of the UGDP. In addition, the Federal Government has twice exercised its right of access to the UGDP raw data to verify the validity of the UGDP findings. When the initial controversy over the UGDP erupted, NIAMDD retained an independent group of biostatisticians, the Biometric Society, to review the UGDP. The Society was given access to the UGDP raw data for this purpose. After conducting a partial audit, it published a report indicating support for the UGDP findings.[20] Several years later, prior to the suspension of new drug applications for phenformin, the FDA conducted its own audit of the UGDP. Details of this audit are sketchy, but the federal defendants admit that the FDA examined and copied at least a sample of the UGDP data in the course of its examination of the study. Gov. Supp. Mem. of Dec. 5, 1977 at 2.

These Government-sponsored or conducted audits are of considerable importance. By examining the UGDP raw data at first hand, the Government has apparently satisfied itself that the UGDP results are sound. In other words, the Government has relied *directly* on the UGDP raw data in the course of formulating official Government policy. As such, these data are precisely the sort of docu-

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[19] The quoted passage refers to statistics from "all available sources," Order at 11, but it is clear from the context that the UGDP is included. The UGDP is also referred to at pp. 8, 38, 40-41, 46, 63 and 66.

[20] Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents, *Report of the Committee for the Assessment of Hypoglycemic Agents*, 231 JAMA 583 (1975).

ments Congress intended to be disclosed under FOIA. *SDC Development Corp. v. Mathews*, *supra* n.3, at 1119-20.[21]

III.

The majority cryptically asserts that a finding that the UGDP raw data are agency "records" would interfere with the "autonomy" of federal grant recipients. The exact meaning of this is unclear. I do not maintain, nor do plaintiffs argue,[22] that the UGDP is a federal "agency." Consequently, no suggestion has been made that all of the various duties and responsibilities of a federal agency should be imposed on the UGDP. The only question before us is whether the UGDP raw data are agency "records" of HEW. An affirmative answer to this question would require *HEW*—not the UGDP—to obtain copies of these records in response to plaintiffs' FOIA request. No direct interference with the manner or method in which a grantee conducts its research would result.

Perhaps the majority's reference to "autonomy" means to suggest that scientific activity would be chilled by the knowledge that data produced under a federal grant

[21] In emphasizing the Government's reliance on the UGDP study and data, I do not imply that the court should give weight to plaintiffs' "need" for the UGDP raw data, or to plaintiffs' position as litigants in the phenformin suspension proceedings. Maj. Op. at 10-11. *See* NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 143 n.10 (1975). My point is simply that, because of the Government's reliance, the UGDP data have been absorbed into the federal decision-making process. This factor, together with the factors previously mentioned—federal funding and federal right of access—satisfies me that the UGDP raw data are agency "records." They should therefore be potentially available for disclosure to *all* members of the public.

[22] Plaintiffs do not challenge the district court's ruling, *see* n.4 *supra*, that the UGDP is not a federal "agency." Pet. Br. at 28 n.7.

could, in limited circumstances, become agency "records." This has been advanced elsewhere as a policy reason for not finding the UGDP data to be agency "records." [23] On closer examination, however, I think even this concern carries little force.

The notion that a chilling effect could result from subjecting the records of federal grantees to disclosure could refer to one of three things. First, it could refer to the possibly inhibiting effect of a visit to the laboratory by a federal official executing a FOIA request. As a basis for restricting FOIA, I find this implausible in the extreme. The inconveniences occasioned by an infrequent FOIA request would be no greater than those currently created by conditions attached to the grant, including the possibility of Government inspection.[24] Yet these burdens appear to have had an imperceptible effect on the enthusiasm for federal research grants.

Secondly, the chilling effect notion could refer to the danger that unscrupulous scientists would use FOIA to appropriate valuable research data for their own credit—or profit. This is a legitimate concern, and if all grantee research records were subject to FOIA it could conceivably deter some scientists from seeking federal grants. But the danger of misappropriation is minimal where, as here, the Government has relied on scientific records in the course of its decisionmaking. Government reliance will likely be limited to cases where the results of the study have been previously published or announced. Thus, whatever weight this concern is entitled to in other con-

[23] Ciba-Geigy Corp. v. Mathews, *supra* n. 3 at 530.

[24] As noted above, HEW grant regulations already give the Government an unlimited right to inspect grantee records. *See* pp. 7-8 *supra*. This right was in fact exercised in this case when the FDA audited the UGDP data.

texts, it is of little significance where the element of reliance is present.

Finally, federal grant applicants might be inhibited by having methodological or investigatory flaws in their work uncovered through a FOIA request. If *this* is the danger the majority seeks to avoid under the guise of protecting grantee "autonomy," then it is a sad day for both the scientific community and the Freedom of Information Act. The essence of the scientific community, I had thought, is the commitment to the advancement of scientific truth by subjecting findings and conclusions to the "exacting scrutiny of fellow experts." [25] Moreover, where scientific data bear the earmarks of agency "records" subject to FOIA, it would be the height of irony to deny disclosure on the ground that it could expose errors or frauds and thereby discourage those who do the work of the Government. FOIA was enacted in part to end the practice of withholding information "only to cover up embarrassing mistakes or irregularities. . . ." S.REP. No. 813, *supra*, at 3. To restrict the definition of agency "records" to accomplish the same end could only be regarded as a giant leap backwards.

I respectfully dissent.

[25] R. MERTON, THE SOCIOLOGY OF SCIENCE 275 (1973); *see also* B. BARBER, SCIENCE AND THE SOCIAL ORDER 89 (1952).

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

February 5, 1976

PETER H. PORSHAM, et al., *Plaintiffs,*

v.

DAVID MATHEWS, et al., *Defendants.*

Order

Upon consideration of plaintiffs' motions for summary judgment and expedited relief, defendant Klimt's motion to dismiss and to quash service of process, federal defendants' motion to dismiss or in the alternative, for summary judgment, the oppositions thereto, the memoranda of the parties in support thereof and in opposition thereto, and the entire record herein, the Court finds that (1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the National Institutes of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) (*See* Affidavits of Theodore M. Cooper, M.D. and G. Donald Whedon, M.D., Federal Defendants' Motion to Dismiss or, in the alternative, for Summary Judgment); (2) the raw data in question is the property of the individual investigators and UGDP study coordinating center and remains in the possession, custody and control of the UGDP study coordinating center (*See* Affidavit of G. Donald Whedon, M.D., *supra*); (3) neither the individual investigators nor the UGDP study coordinating

center is an "agency" within the purview of the Freedom of Information Act, 5 U.S.C. § 552;[1] and (4) consequently, the raw data in issue are not "agency records" subject to the disclosure provisions of the Freedom of Information Act, 5 U.S.C. § 552(B).

It is, accordingly, by the Court this 5th day of February, 1976,

ORDERED that plaintiffs' motion for summary judgment should be, and the same is hereby, denied. And it is further

ORDERED that defendants' motions to dismiss should be, and the same are hereby, granted.[2]

/s/ HOWARD CORCORAN
Judge

[1] For purposes of the FOIA, an "agency" includes "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency." 5 U.S.C. § 552(e).

[2] The remaining motions for expedited relief and to quash service of process are denied as moot.

APPENDIX D

5 U.S.C. § 552

Title 5

Government Organization and Employees

CHAPTER 5—ADMINISTRATIVE PROCEDURE

Part I—The Agencies Generally

SUBCHAPTER II—ADMINISTRATIVE PROCEDURE

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general

policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and

(C) administrative staff manuals and instructions to staff that affect a member of the public;

unless the materials are promptly published and copies offered for sale. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction. However, in each case the justification for the deletion shall be explained fully in writing. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967,

and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(4)(A) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying a uniform schedule of fees applicable to all constituent units of such agency. Such fees shall be limited to reasonable standard charges for document search and duplication. Documents shall be furnished without charge or at a reduced charge where the agency determines that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action.

(C) Notwithstanding any other provision of law, the defendant shall serve an answer to otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the

withholding, the Civil Service Commission shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Commission, after investigation and consideration of the evidence submitted, shall submit its findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Commission recommends.

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall—

(i) determine within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular request—

(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(C) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request Any notification of denial of any request for

records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(b) This section does not apply to matters that are—

(1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the

case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(d) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include—

(1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(2) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;

(4) the results of each proceeding conducted pursuant to subsection (a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) a copy of every rule made by such agency regarding this section;

(6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and

(7) such other information as indicates efforts to administer fully this section.

The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsections (a)(4)(E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(e) For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 383; Pub.L. 90-23, § 1, June 5, 1967, 81 Stat. 54; Pub.L. 93-502, §§ 1-3, Nov. 21, 1974, 88 Stat. 1561-1564; Pub.L. 94-409, § 5(b), Sept. 13, 1976, 90 Stat. 1247.

APPENDIX E

HEW Regulations Governing Administration of Grant Research

Title 45—Public Welfare

Subtitle A—Department of Health, Education, and Welfare

Part 6—Inventions and Patents (General)

§ 6.1 Publication or patenting of inventions.

It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made where the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Commissioner of Patents. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

[23 FR 2990, Mar. 27, 1963. Redesignated at 31 FR 12842, Oct 1, 1966]

Title 45—Public Welfare

Subtitle A—Department of Health, Education, and Welfare

Part 8—Inventions Resulting From Research Grants, Fellowship Awards, and Contracts For Research

§ 8.0 Policy.

(a) The Department of Health, Education, and Welfare each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application. The scientific and technological advances attributable, in varying degrees to this expenditure of public funds frequently include patentable inventions.

(b) The Department, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

(c) On the other hand, in some cases it may be advisable to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Department has a responsibility to see that the public use of the

fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

§ 8.1 Conditions to be included in research grants.

Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide either

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs) or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the Assistant Secretary (Health and Scientific Affairs) finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be

prescribed, to file foreign patent applications upon the invention.

[20 FR 6749, Sept. 14, 1965, as amended at 31 FR 12842, Oct. 1, 1966]

Title 45—Public Welfare

Subtitle A—Department of Health, Education, and Welfare

Part 74—Administration of Grants

Subpart D—Retention and Custodial Requirements for Records

§ 74.20 Length of retention period.

HEW will not impose record retention requirements over and above those established by the grantee except that financial records, supporting documents, statistical records, and all other records pertinent to an HEW grant shall be retained for a period of three years. This requirement applies to the pertinent records and documents of grantees, subgrantees, and recipients under grants or subgrants of negotiated contracts (or subcontracts) exceeding $10,000. The requirement is qualified as follows:

(a) If audit by or on behalf of the Federal Government has begun but is not completed at the end of the three-year period, or if audit findings have not been resolved at the end of the three-year period, the records shall be retained until resolution of the audit findings. In no case, however, will HEW require retention of records relating to any grant with respect to which actions by the United States to recover for diversion of money paid under the grant are barred by the statute of limitations in 28 U.S.C. 2451(b).

(b) In order to avoid duplicate recordkeeping, granting agencies may make special arrangements with grantees to retain any records which are continuously needed for joint use. The granting agency will request transfer of records to its custody from grantees when it determines that the records possess long-term retention value. When the rec-

ords are transferred to or maintained by HEW, the three year retention requirement is not applicable to the grantee.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.23 Access to records.

(a) HEW and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the grantee which any of them determine are pertinent to a specific HEW grant, for the purpose of making audit; examination, excerpts and transcripts.

(b) In the case of a subgrant (or negotiated contract or subcontract exceeding $10,000) under a HEW grant, the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee (or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives determine are pertinent to the specific HEW grant, for the purpose of making audit, examination, and transcripts.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.24 Restrictions on public access.

Unless otherwise required by law, HEW will not place restrictions on grantees which will limit public access to the grantee's records or to the records of their subgrantees

or contractors, except when the records must remain confidential for any of the following reasons:

(a) To prevent a clearly unwarranted invasion of personal privacy;

(b) To comply with an executive order or statute which specifically requires the records to be kept secret; or

(c) To protect commercial or financial information obtained from a person or firm on a privileged or confidential basis.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44553, Oct. 8, 1976]

APPENDIX F

Pertinent FDA Regulations Governing Disclosure of Data

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 12.35, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding up to that time. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be placed on public display and shall not be part of the administrative record of that proceeding.

(2) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(3) All other documentary data and information on which he relies.

(4) A narrative statement of his position on the factual issues stated in the notice of hearing and the type of evidence he intends to introduce in the hearing in support of his position.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within 60 days after the notice of hearing is published in the FEDERAL REGISTER pursuant to § 12.35, or, where no participant will be prejudiced, within such shorter or longer period of time as the presiding officer orders, each

participant shall submit to the Hearing Clerk all data and information specified in paragraph (a) (2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a) (1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen at that time.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall also constitute a waiver of the right to a hearing.

(e) Any documentary data and information submitted by one participant may be referenced by another. Participants are encouraged to exchange and consolidate lists of documentary evidence prior to reproducing it for submission to the Hearing Clerk in order to reduce duplicative submissions. If a particular document is bulky or is in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, a participant may request the presiding officer for permission to submit a reduced number of copies to the Hearing Clerk.

(f) The presiding officer shall rule on questions relating to this section.

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

Part 20—Public Information

Subpart F—Availability of Specific Categories of Records

§ 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of "markers" to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

Part 312—New Drugs For Investigational Use

Subpart A—Exemptions From Section 505(a)

§ 312.1 Conditions for exemption of new drugs for investigational use.

(a) A shipment or other delivery of a new drug shall be exempt from section 505(a) of the act if all the following conditions are met:

• • •

(4) The sponsor maintains adequate records showing the investigator to whom shipped, date, quantity, and batch or code mark of each such shipment and delivery, until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. Upon the request of a scientifically trained and properly authorized employee of the Department at reasonable times, the sponsor makes the records referred to in this subparagraph and in paragraph (a)(2) of this section available for inspection, and upon written requests submits such records or copies of them to the Food and Drug Administration. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

• • •

(13) The sponsor shall obtain from each investigator involved in clinical trials a signed statement in the following form:

Form FD-1573

Department of Health, Education, and Welfare, Food and Drug Administration

Statement of Investigator

• • •

4. The undersigned understands that the following conditions, generally applicable to new drugs for investigational use, govern his receipts and use of this investigational drug:

• • •

e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new drug applications is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.